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MINISTRY OF
AGRICULTURE, FISHERIES AND FOOD

FOOD ADDITIVES AND CONTAMINANTS COMMITTEE REPORT ON THE REVIEW OF THE EMULSIFIERS AND STABILISERS IN FOOD REGULATIONS, 1962

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FOOD ADDITIVES AND CONTAMINANTS COMMITTEE

The terms of reference of the Food Additives and Contaminants Committee are:

"To advise the Minister of Agriculture, Fisheries and Food, the Secretary of State for Scotland, the Secretary of State for Social Services, and as respects Northern Ireland, the Secretary of State for the Home Department, on matters referred to them by Ministers, in relation to food contaminants, additives and similar substances which are or may be present in food, or used in its preparation, with particular reference to the exercise of powers conferred on Ministers by Sections 4, 5 and 7 of the Food and Drugs Act, 1955, and the corresponding provisions in enactments relating to Scotland and Northern Ireland."

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"To advise at the request of the Committee on Medical Aspects of Food Policy, the Food Additives and Contaminants Committee, the Ministry of

Agriculture, Fisheries and Food, the Department of Health and Social Security, the Scottish Home and Health Department, or the Ministry of Health and Social Services, Northern Ireland on the hazard to health, including toxicological and carcinogenic risks, resulting from the use or presence of additives or contaminants in or on food."

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FOOD ADDITIVES AND CONTAMINANTS COMMITTEE REVIEW OF THE EMULSIFIERS AND STABILISERS IN FOOD REGULATIONS, 1962

Remit

1. A review of The Emulsifiers and Stabilisers in Food Regulations, 1962 was announced in 1963 and representations from interested parties were invited. These were referred to the Food Additives and Contaminants Sub-Committee of the Food Standards Committee in 1964. The present Committee when it was established in November 1964 took over the review.

Background to the Review

2. The Emulsifiers and Stabilisers in Food Regulations, 1962 (Appendix II) were made in April 1962 and came into force in July 1962. The Regulations were based mainly on the Food Standards Committee Report on Emulsifying and Stabilising Agents, 1956 which had recommended a statutory permitted list. Following representations on the Report the Regulations permitted a wide range of substances which were actually in use in 1962 and grouped most of them together by classes (e.g. "complete glycerol esters"). It was therefore decided to begin a review of the Regulations in advance of the customary five-year period.

Uses of Emulsifiers and Stabilisers and Definitions

3. Emulsifiers and stabilisers are necessary and widely used in the production of such foods as bread, flour confectionery, ice-cream, margarine, chocolate and sugar confectionery, some soft drinks and milk products. In recent years there has been an increase in the number of convenience foods which has been facilitated greatly by the development of new or improved emulsifiers and stabilisers.

4. The Regulations contain the following definitions:

> " 'emulsifier' and 'stabiliser' mean respectively any substance, other than a natural food substance, which is capable—
>
> (*a*) in the case of an emulsifier, of aiding the formation of, and
>
> (*b*) in the case of a stabiliser, of maintaining,
>
> the uniform dispersion of two or more immiscible substances . . . . . ."
> [the definition then lists specific exceptions—see paragraph 10].
> " 'natural food substance' means any substance, suitable for use as food and commonly used as food, which is wholly a natural product, whether or not that substance has been subjected to any process or treatment."

We accept these definitions which have stood the test of time although we propose to qualify the term "process or treatment" in order to deal with modified starches (paragraph 11).

A Revised Permitted List

5. The present permitted list in the First Schedule to the 1962 Regulations consists of seven groups of substances and three individual substances. We found it impossible to assess the need for, or safety-in-use of, each of the substances included in the seven groups without considering them individually. We therefore considered separately the individual substances and the chemically and metabolically closely related substances which were known to us and which came within one or other of the groups. We have similarly studied all substances submitted to us for addition to the permitted list; as well as those substances or groups of substances which may be used in food because, though capable of acting as emulsifiers and stabilisers, they are specifically excluded from the definition of "emulsifier" and "stabiliser" given in the 1962 Regulations. *We recommend* that the revised permitted list should consist only of individual substances or, if necessary, of technical mixtures of closely related substances. *We also recommend* that the number of specific exclusions from the definition of "emulsifier" and "stabiliser" should be significantly reduced as indicated at paragraphs 9 to 15 below.

6. We consider it essential that the permitted list be accompanied by compositional and purity specifications. This will not be easy because of the wide range of commercial products most of which are of heterogeneous composition and many of which do not have published specifications. Appendix III includes the published specifications which are available, or the specifications which can be drawn up from available information. *We recommend* that emulsifiers and stabilisers for which specifications are given in Appendix III should be permitted subject to those specifications and that other emulsifiers and stabilisers should be permitted only if specifications adequate for inclusion in revised Regulations are made available by manufacturers or by those wishing to use such substances.

7. We recognise that these recommendations, together with our recommendations based on the toxicological assessment of individual and closely related substances will mean that some emulsifiers and stabilisers now in use will not be permitted in future and that more toxicological work will be required on others if they are to continue to be permitted after the next review. However, it is now generally accepted as necessary and not merely desirable that the safety-in-use of an additive should satisfy the criteria laid down in Part II of the Memorandum on Procedure for Submissions on Food Additives and on Methods of Toxicity Testing, 1965 except where expert advice is that an exemption can be justified.

Report of the Pharmacology Sub-Committee

8. The report of the Pharmacology Sub-Committee is attached as an Annex to this report. We have re-affirmed above what the Sub-Committee says about the importance of and the need for adequate specifications. The Pharmacology Sub-Committee have classified substances into certain toxicological groups (Annex—paragraphs 5 to 9). *Group A* are additives which the available evidence suggests are acceptable for use in food; *Group B* are additives which the available evidence suggests may be regarded in the meantime as provisionally acceptable but about which further information is necessary and which must be reviewed within a specified period. *We recommend* that only substances classified by the Pharmacology Sub-Committee as Group A or Group B be included in the

permitted list. *We further recommend* that each substance placed in Group B should again be reviewed not later that five years after the making of regulations and that any substance for which satisfactory evidence has not been received by then should be withdrawn from the permitted list. It is usual to consider whether there is a need to place restrictions on the extent to which substances placed in Group A or Group B may be allowed for use in food and in this case we propose certain restrictions which are discussed in paragraphs 16 to 24 and 26 and 28. On the evidence at present available we do not consider that the substances placed in Group E (for which the available evidence was inadequate to enable an opinion to be expressed as to their suitability for use in food) should be included in the permitted list, but this decision could be re-examined if additional evidence were submitted on need and safety-in-use.

Substances at present excluded from the definition of Emulsifier and Stabiliser

9. We have already recommended (at paragraph 5 above) that the number of exclusions from the definition of "emulsifier" and "stabiliser" should be reduced. *We recommend* that in future all emulsifiers and stabilisers accepted for use in food should, as far as is practicable, be included in the permitted list.

10. We have considered the substances which at present are used in food, often as emulsifiers or stabilisers, but which are specifically excluded from the definition of "emulsifier" and "stabiliser" in the 1962 Regulations and have reached the following conclusions:

(*a*) *Agar* (A), *alginic acid* (A), *calcium alginate* (A), *sodium alginate* (A), *carrageen* (A), *edible gums* [acacia (A), karaya (A), tragacanth (A), carob (A), ghatti (B), guar (B)], *pectin* (A), *calcium pectate* (A), *sodium pectate* (A), and *quillaia* (B) [but see paragraph 23], have been classified as Group A or as Group B—as indicated in parentheses. *We recommend* that they be included in the revised permitted list.

(*b*) *Calcium chloride* (A), *calcium lactate* (A), *sorbitol* (A), the *sodium and potassium salts* of *acetic* (A), *carbonic* (A), *citric* (A), *lactic* (A), *malic* (A), *phosphoric* (A), *polyphosphoric* (A), and *tartaric* (A) *acids* have all been recommended for inclusion on permitted lists in our Report on Further Classes of Food Additives, 1968.

(*c*) *Lecithin*, *calcium caseinate* and *sodium caseinate* have been used for many years and we are aware of no hazard from their use. *We recommend* that they be included in the permitted list.

(*d*) We consider that *proteins* (*whether hydrolysed or not*) and *malt extract* may properly be used and that they would fall within the term "natural food substance". *We recommend* that they should continue to be defined out of the Regulations in a revised definition of natural food substances but that the former should be referred to more precisely as proteins, protein concentrates and protein hydrolysates (see paragraph 11).

(*e*) *Dextrins* and *starches* (*whether modified or not*) are a most important but complex group of substances the use of some of which, especially modified starches, has been increasing rapidly since the 1962 Regulations were made. We were greatly assisted by the provision of a large amount of detailed information by the food and starch industries who informed us that they attached great importance to being able to continue to use all the substances without restriction. They further contended that most starches, in contrast to other emulsifiers and stabilisers, were foods in their own right. Therefore the trade strongly urged that if any control over starches were necessary, this should be effected by separate legislation. We do not accept that it is necessary or particularly advantageous to control, by means of separate legislation, those starch products capable of acting as emulsifiers or as stabilisers. Our detailed views are given in paragraphs 11 to 15 below.

Starches and Modified Starches

11. *Natural starches* may safely and properly be permitted and *we recommend* that this be done by retaining in the revised Regulations a modified definition of "natural food substance" as follows:

> " 'natural food substance' means any substance, suitable for use as food and commonly used as food, which is wholly a natural product, whether or not that substance has been subjected to any process or treatment and includes proteins, protein concentrates and protein hydrolysates, malt extract, glucose syrups, starches, acid-thinned starches and dextrins, but does not include starch products resulting from a process of chemical modification (such as oxidation, cross-linking, esterification and etherification) or from a process of enzyme modification (other than malt extract and glucose syrups)".

12. All natural starches, e.g. maize, wheat, potato, tapioca, are thick boiling starches. Therefore the solids content of hot solutions must be low in order to obtain workable viscosities and this can be a disadvantage. Modifications are carried out to adapt certain properties such as viscosity, dispersibility and ease of gelatinisation to requirements for specific use. Modification is not restricted to chemical processing but can also be obtained by physical means, e.g. pregelatinised starch or by selective plant breeding, e.g. amylopectin starch or by enzyme treatment. Chemically modified starches can be divided into "converted starches" in which treatment with acids, oxidising agents or enzymes results mainly in a reduction in the size of the starch molecule and "substituted starches" in which a substituent group is introduced into the glucose units. Both processes are applied to modify the physical characteristics of unprocessed starches.

13. We cannot accept that these kinds of chemical and enzyme modifications may properly be ignored; they change the composition of the natural food starch (albeit to a minor extent) and it is possible that in some cases—especially where substituent groups are introduced—there could be some hazard to the consumer. Therefore, such modified starches cannot be excluded from control.

14. The available information about specifications and toxicity testing was somewhat limited. We and the Pharmacology Sub-Committee have carefully examined all the information which was submitted to us. We were impressed by the wide variety of substances and their special properties. We are not yet convinced however that there is a need for all of them to be included in a permitted list. As a large number of important modified starches has been classified as Group A or Group B, we are unable to recommend at present that those substances which have been placed in Group E (for which the available

evidence was inadequate to enable an opinion to be expressed as to their suitability for use in food) should be permitted until further evidence on need and safety-in-use has been provided.

15. *We recommend* that the following modified starches be included in a revised permitted list:

- (*a*) *Bleached (lightly oxidised) starches* (A)
- (*b*) *Hypochlorite oxidised starches* (A)
- (*c*) *Di-starch phosphate* (modified with sodium trimetaphosphate) (A)
- (*d*) *Di-starch phosphate* (modified with phosphoryl chloride) (B)
- (*e*) *Phosphated di-starch phosphate* (B)
- (*f*) *Di-starch glycerol* (B)
- (*g*) *Starch acetates* (B)
- (*h*) *Acetylated di-starch glycerol* (B)
- (*i*) *Acetylated di-starch adipate* (B)

We further recommend that modified starches (*c*) to (*i*) may be acid-thinned and/or bleached.

The Need for Restrictions on Use

16. The present Regulations restrict the emulsifiers and stabilisers that may be used in bread. We received representations that there should be no such restrictions and that where a substance was considered to be safe-in-use its use should be permitted freely in any food. While we see no reason in principle to restrict particular substances unduly once a case for need has been established, we consider that it is right to treat bread differently and also that restrictions should be imposed in particular cases where there are good reasons for doing so.

Bread

17. We therefore propose to restrict the emulsifiers and stabilisers that may be used in bread in accordance with the view expressed by our predecessors when first reviewing this class of additives (Food Standards Committee Report on Emulsifying and Stabilising Agents*: paragraph 33) and again in the Report on Bread and Flour† (paragraphs 59 and 60). *We recommend* that only *stearyl tartrate* (A), *commercial mono- and di-glycerides of fatty acids* (A) and *diacetyl tartaric acid esters of mono- and di-glycerides* (B) be permitted in bread. *We further recommend* that *lecithin* continue to be permitted. We would be prepared to consider during the Review of The Bread and Flour Regulations, 1963 the necessity for a specific provision to allow the "carry-over" into bread of *octadecylamine acetate* (B) by reason of its use as an anti-caking agent in yeast food (see paragraph 24).

18. We received no evidence that there is a need for *lactoglycerides* (B) for use in bread. We received representations that *partial polyglycerol esters* be permitted in bread, since shortenings containing this emulsifier, delivered for use in flour confectionery, might inadvertently be used in bread manufacture. We do not consider that it would be right that legislation should be expected to deal with this sort of situation and cannot agree to it.

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* HMSO 1956.

† HMSO 1960.

19. We were asked to widen the provisions of The Bread and Flour Regulations, 1963, to enable a *bread improver* which consists of a permitted emulsifier, edible gum and cornflour to be used. Edible gum and cornflour are not amongst the permitted ingredients of bread listed in The Bread and Flour Regulations, 1963. *We recommend* that this representation can best be considered when we are reassessing the list of permitted additives for bread and flour in the forthcoming review of The Bread and Flour Regulations, 1963.

Special Restrictions on Certain Emulsifiers and Stabilisers

20. **We have considered** the use of *sorbitan and polyoxyethylene sorbitan esters of fatty acids* in certain foods taking account of recommendations of the Pharmacology Sub-Committee. We consider that they should not be used in bread, potatoes (or potato products), milk products, meat products, fish products, ice-cream, baby and infants foods, margarine and cooking fats. We would be prepared to consider recommendations for use in foods which are not significant items in the normal diet. We take the same view about *dioctyl sodium sulphosuccinate* and *we recommend* accordingly.

Cream

21. Thickening substances have been banned since 1925 in cream and reconstituted cream. We were consulted by the Food Standards Committee during their review of cream about the use of stabilisers in certain circumstances. Our advice, which was included in paragraph 46 of the Food Standards Committee Report on Cream issued in 1968, was that the ban on thickening substances should be maintained but that *sodium alginate* (A) and *sodium carboxymethyl cellulose* (A) could be allowed in whipped cream at up to 0·3 per cent by weight. We received representations under this Review, which we accept, that *dextrose* should also be exempted from the definition of thickening substance as well as cane sugar and beet sugar, which we prefer to express as "sucrose". We suggest that *fructose* should likewise be accepted. *We recommend* accordingly.

Flour, Milk and Other Foods

22. We confirm that flour, when sold as such, should not be permitted to contain any emulsifier or stabiliser. None may be used in milk. Apart from the restrictions proposed above, we do not consider that there need be any other restrictions relating to the use of emulsifiers and stabilisers in particular foods.

Restrictions on Amounts to be Used

23. We have again considered whether it is necessary or desirable to specify maximum amounts which may be used generally or specifically in foods. We are aware that some of the international standards now being elaborated include such limits. However, except for cream, we do not consider that limits need be laid down unless it is necessary to do so on toxicological advice. Good manufacturing practices will ensure that only the correct amounts of these relatively expensive substances are used particularly as in some cases excess amounts will give unacceptable results. Having regard to the advice of the Pharmacology Sub-Committee, *we recommend* that *quillaia* (B) should be restricted to soft drinks at a maximum level of 200 ppm.

24. We considered whether it was necessary to provide for the carry-over of up to 0·5 ppm *octadecylamine* (B) into food from the practice of adding this substance to protect steam boiler systems from corrosion. We consider that the effects of the practice of direct steam heating should be made the subject of a review and we therefore consider it inappropriate to make any recommendations about this particular contaminant in this Report. The contamination by this Group B substance at such a low level does not seem to warrant concern.

Partial Glycerol and Partial Polyglycerol Esters—Permitted Level of Sodium/Potassium Salts of Fatty Acids

25. Partial glycerol esters as defined in the Regulations may contain up to 2 per cent by weight of the sodium salt of any fatty acid present. We received representations that the potassium salts should also be allowed, that the permitted presence of such salts be extended to partial polyglycerol esters and that, for technological reasons, the permitted level should be increased to 6 per cent. We accept that it may be necessary to include up to 6 per cent sodium or potassium salts, or mixtures of these salts to the same level, in self-emulsifying grades of partial gylcerol and partial polyglycerol esters so that they will disperse readily in water—particularly in "hard" water. *We recommend* that this be allowed in a revised definition or that a suitable provision be made in the relevant specifications.

Tin-greasing Emulsions

26. Under the present Regulations [regulation 3(5)(*b*)], food may contain an emulsifier or stabiliser which is not on the permitted list if it is present solely because of its use in a tin-greasing emulsion used during the preparation of food. We do not consider it necessary to provide for this exemption. Permitted emulsifiers are already used and so are release agents (including edible oils) which have been dealt with in our Report on Further Classes of Food Additives, 1968. *Oxidatively polymerised oils* ("blown" oils) which are not on the currently permitted list, are said to be fairly extensively used. One such oil—an *oxidatively polymerised soyabean oil*—has been classified by the Pharmacology Sub-Committee as provisionally acceptable for use in tin-greasing emulsions and we think it should be specifically allowed for that purpose. The observations of the Pharmacology Sub-Committee on blown oils confirm our view that we ought to change the present latitude given in the current Regulations towards the use of emulsifiers in tin-greasing emulsions. *We recommend*, therefore, that the present general exemption for such substances be withdrawn and that *oxidatively polymerised soyabean oil* should be included in the list of permitted emulsifiers for use in tin-greasing emulsions up to a limit of 50 ppm in any food, including bread and any other food which might be subject to any special restrictions.

Substances which have Not been Recommended because a case for Need has Not been Established

27. We regard it as an important part of our responsibilities to consider and evaluate the need for each additive or group of additives which industry wishes to use in food. We have considered carefully all the available evidence about the under-mentioned substances which are either permitted now by virtue of the present system of groups of substances or which have been submitted to us during the Review.

28. We received representations for the use of *polyoxyethylene stearates* on the grounds that it appeared illogical not to permit them as polyoxyethylene sorbitan derivatives were allowed. However, so far as we know, *polyoxyethylene stearates* have not been generally permitted for use in any other country and it is difficult to see any reason why they need be allowed here. We consider that in the absence of a considered case that these substances are needed, a recommendation for their use could not properly be given at the present time, especially in view of the number of other emulsifiers and stabilisers which are being recommended.

29. *Monostearin sodium sulphoacetate* does not appear to be used as far as we can ascertain and as there appears to be no demand for it in the United Kingdom, we make no recommendation for its inclusion in the permitted list. *Cetomacrogol 1000* (*Polyethylene glycol 1000 monocetyl ether*) and *Solvitose Gum OH-40* [*Hydroxypropyl ether of locust bean* (*Ceratonia siliqua*) *gum*] have been submitted but without the necessary toxicological data. In the circumstances we cannot recommend their inclusion especially as the need for them over and above those we have recommended has not been established to our satisfaction. For similar reasons we cannot recommend *sodium carboxymethyl galactomannose* or *pentaerythritol stearates.*

30. We have already recommended that the number of emulsifiers and stabilisers permitted in bread needs to be kept to the minimum. *Stearyl lactylic acid, calcium stearyl dilactylate, stearyl monoglyceride citrate* and *sodium monostearyl fumarate* were submitted for use in bread and in some other bakery products. The toxicological evidence on these substances is incomplete and although they are allowed in the U.S.A., we do not consider that in United Kingdom conditions there is a need for them.

31. The use of *calcium sucrose phosphate* is in the development stage primarily as a prophylactic against tooth decay. We do not recommend its inclusion in the permitted list for the time being.

32. *Hydroxylated lecithin* was submitted to us for use in a specific product but we now understand that it has been found possible to use an acceptable alternative.

Representations on Other Provisions of the Regulations

33. The term "inter-esterification" is defined in the 1962 Regulations. It has been represented that this term would be more accurately expressed as "internal-interesterification". However, "internal-interesterification" does not seem suitable since it implies an *intra*molecular reaction whereas the fatty acids in the partial polyglycerol ester of the inter-esterified fatty acids of castor oil are linearly polymerised by an *inter*molecular condensation. The term "poly-condensed" is more suitable and *we recommend* it should be used.

Labelling and Advertising of Emulsifiers and Stabilisers

34. We received representations that regulation 5(2) of the 1962 Regulations taken in conjunction with regulation 3 could be interpreted to mean that foods containing an emulsifier or stabiliser should be sold in a container and be labelled in accordance with the Second Schedule to the Regulations. We do not think this was intended and *we recommend* that, if necessary, this point be

clarified when the revised Regulations are drafted. We received representations also that trade terms such as "G.M.S." (i.e. glyceryl monostearate) should not be used without further qualification. We agree, but in view of the terms of Schedule 2 to the Regulations we do not think it necessary to make any recommendations on the point.

35. We received representations about regulation 6(2)(*b*) which relates to the advertisement of emulsifiers. The provision is as follows:

> "publish or be party to the publication of, any advertisement of any permitted emulsifier or permitted stabiliser for sale which bears or includes any statement which is calculated to imply either directly or by ambiguity, omission or inference that that emulsifier or stabiliser is a substitute for fat or eggs."

We were asked to agree that the words "fat or" be omitted. It was suggested that the present provision had been included to prohibit during the War the advertising of emulsions containing large quantities of water as being a substitute for fat or eggs. It is true that some emulsifiers are very similar to fat and have similar nutritional value. Nevertheless, we consider it to be undesirable for manufacturers to advertise that the fat content of a product which is a natural constituent could be reduced by the use of an emulsifier which is not. *We recommend* that the provision be retained in the present form.

Review

36. *We recommend* that any Regulations made as a result of the Report should be reviewed not more than five years after they are made.

Summary of Recommendations

37. (i) The revised permitted list should consist only of individual substances or, if necessary, of technical mixtures of closely-related substances (paragraph 5).

(ii) The number of specific exclusions from the definition of "emulsifier" and "stabiliser" should be significantly reduced (paragraph 5).

(iii) Specifications for emulsifiers and stabilisers in Appendix III should be laid down and others should be permitted only if specifications adequate for inclusion in the revised Regulations are made available by manufacturers or by those wishing to use such substances (paragraph 6).

(iv) Only substances classified by the Pharmacology Sub-Committee as Group A or Group B should be included in the permitted list (paragraph 8).

(v) Each substance placed in Group B should again be reviewed not later than five years after the making of the Regulations, and any substance for which satisfactory evidence has not been received by then should be withdrawn from the permitted list (paragraph 8).

(vi) All emulsifiers and stabilisers accepted for use in food should, as far as practicable, be included on the permitted list (paragraph 9).

(vii) The following which are at present specifically excluded should be specifically included in the revised permitted list:

Group A
Agar
Alginic acid
Calcium alginate

Sodium alginate
Carrageen
Acacia
Karaya
Tragacanth } edible gums
Carob
Pectin
Calcium pectate
Sodium pectate

Group B
Ghatti
Guar } edible gums
Quillaia
(see also (xvii) below)

(paragraph 10(*a*))

(viii) Lecithin, calcium caseinate and sodium caseinate should be included in the permitted list (paragraph 10(*c*)).

(ix) Proteins, protein concentrates, protein hydrolysates and malt extract should be defined out of the Regulations in a revised definition of "natural food substance" (paragraph 10(*d*)).

(x) Natural starches may be permitted by means of a revised definition of "natural food substance" as follows:

> " 'natural food substance' means any substance, suitable for use as food and commonly used as food, which is wholly a natural product, whether or not that substance has been subjected to any process or treatment and includes proteins, protein concentrates and protein hydrolysates, malt extract, glucose syrups, starches, acid-thinned starches and dextrins, but does not include starch products resulting from a process of chemical modification (such as oxidation, cross-linking, esterification and etherification) or from a process of enzyme modification (other than malt extract and glucose syrups)" (paragraph 11).

(xi) Starch products resulting from a process of chemical or enzyme modification cannot be excluded from control (paragraph 13).

(xii) The following modified starches should be included in a revised permitted list:

- (*a*) Bleached (lightly oxidised) starches (A).
- (*b*) Hypochlorite oxidised starches (A).
- (*c*) Di-starch phosphate (modified with sodium trimetaphosphate) (A).
- (*d*) Di-starch phosphate (modified with phosphoryl chloride) (B).
- (*e*) Phosphated di-starch phosphate (B).
- (*f*) Di-starch glycerol (B).
- (*g*) Starch acetates (B).
- (*h*) Acetylated di-starch glycerol (B).
- (*i*) Acetylated di-starch adipate (B).

Modified starches (*c*) to (*i*) may be acid-thinned and/or bleached (paragraph 15).

(xiii) Only stearyl tartrate (A), commercial mono and di-glycerides of fatty acids (A) and diacetyl tartaric acid esters of mono- and di-glycerides (B) should be permitted in bread; and lecithin should continue to be permitted (paragraph 17).

(xiv) The representation that The Bread and Flour Regulations, 1963 should be widened to enable a bread improver consisting of a permitted emulsifier, edible gum and cornflour to be used, should be considered in the context of the review of The Bread and Flour Regulations, 1963 (paragraph 19).

(xv) Sorbitan and polyoxyethylene sorbitan esters of fatty acids should not be used in bread, potatoes (or potato products), milk products, meat products, fish products, ice-cream, baby and infant foods, margarine and cooking fats. Their use may be considered in foods which are not significant items in the normal diet. The same view is taken about dioctyl sodium sulphosuccinate (paragraph 20).

(xvi) The ban on thickening substances in cream should be maintained, but sodium alginate (A) and sodium carboxymethyl cellulose (A) could be allowed in whipped cream up to 0·3 per cent by weight. Dextrose and fructose should be specifically exempted from the definition of thickening substance, in addition to cane sugar and beet sugar which should be expressed as 'sucrose' (paragraph 21).

(xvii) Quillaia (B) should be restricted to soft drinks at a maximum level of 200 ppm (paragraph 23) (see also (vii) above).

(xviii) Provision should be made to allow the potassium salts as well as the sodium salts of the fatty acid present in self-emulsifying grades of partial glycerol esters; that up to 6 per cent by weight of either salt, or 6 per cent of a mixture of the salts should be permitted; and this provision should be extended to partial polyglycerol esters (paragraph 25).

(xix) The present general exemption from the Regulations of emulsifiers used in tin-greasing emulsions should be withdrawn. Oxidatively polymerised soyabean oil (a blown oil) should be included for use in tin-greasing emulsions in the permitted list of emulsifiers, with a limit of 50 ppm in any food, including bread and other restricted foods (paragraph 26).

(xx) The term "polycondensed" should replace the term "inter-esterified" (paragraph 33).

(xxi) The question whether regulation 5(2) read in conjunction with regulation 3 could be interpreted to mean that foods containing an emulsifier or stabiliser should be sold in a container and be labelled in accordance with the Second Schedule to the Regulations should be clarified, if necessary, when revised Regulations are drafted (paragraph 34).

(xxii) The provision in regulation 6(2)(*b*), relating to the advertisement of emulsifiers should be retained in its present form (paragraph 35).

(xxiii) Any Regulations made as a result of the report should be reviewed not more than five years after they are made (paragraph 36).

Table of Recommendations on Individual Substances

38. A table of recommendations on individual substances has been included as Appendix IV.

FAC/REP/9

July, 1969
February, 1970

LIST OF THOSE WHO MADE REPRESENTATIONS OR GAVE INFORMATION

Advita Ltd.
Aktieselskabet Grindstedvaerket
Alginate Industries Ltd.
Armour Hess Chemicals Ltd.
Association of Manufacturers of Shortening and Compound Cooking Fat
Alfred Bird Ltd.
Victor Blagden & Co. Ltd.
Boake Roberts & Co. Ltd.
Fredk. Boehm Ltd.
Bowmans Chemicals Ltd.
British Arkady Co. Ltd.
British Bakels Ltd.
British Celanese Ltd.
British Essence Manufacturers' Association
British Food Manufacturing Industries Research Association
British Industrial Biological Research Association
British Paper and Board Makers' Association
British Soft Drinks Council
British Standards Institution
H. P. Bulmer & Co. Ltd.
Cadbury Bros. Ltd.
Cake and Biscuit Alliance Ltd.
Central Milk Distributive Committee
City of Birmingham County Borough
C.J.P. (Produce) Ltd.
Cocoa, Chocolate and Confectionery Alliance
Colonial Sugar Refining Co. Ltd.
Co-operative Wholesale Society Ltd.
Corn Products Ltd.
County Councils Association
Croda Edible Compounds Ltd.
Cyanamid of Great Britain Ltd.
Dow Chemical Co. (U.K.) Ltd.
Emulsion A/S
Fisons Foods Ltd.
Flour Milling and Baking Research Association
Food Industries Ltd.
Food Machinery Association
Food Manufacturers Federation Incorporated
Forsters Glass Co. Ltd.
Garton, Sons & Co. Ltd.
Glass Manufacturers Federation
Glovers (Chemical) Ltd.
Gordon Slater Ltd.
Hammetts Dairies Ltd.

Bernard Hawley and Associates
Thomas Hedley & Co. Ltd.
Hercules Powder Co. Ltd.
Honeywill—Atlas Ltd.
Honeywill and Stein Ltd.
Houseman and Thompson Ltd.
Howards of Ilford
Huntingdon Research Centre
Ice Cream Alliance
Imperial Chemical Industries Ltd.
Kodak Ltd.
Kraft Food Ltd.
Lautier Fils Ltd.
Margarine Manufacturers' Association
T. McLachlan and Partners
Midland Silicones
Milk Marketing Board
Monsanto Chemicals Ltd.
National Dairymens' Association
Northern Ireland Milk Marketing Board
Parliamentary Committee (Co-operative Union Ltd.)
Pfizer Ltd.
Scottish Milk Marketing Board
Skip Co. Ltd.
Soya Food Ltd.
Spillers Ltd.
Stevenson & Howell Ltd.
Charles Tennant & Co. Ltd.
Tunnel Avebe Starches Ltd.
Tunnel Refineries Ltd.
Unilever Ltd.
Unilever—Emery N.V.
Vesop Products Ltd.
Witco Chemical Co. Ltd.

THE EMULSIFIERS AND STABILISERS IN FOOD REGULATIONS, 1962

(Statutory Instrument 1962, No. 720)

This appendix has been prepared in order to facilitate reference by the reader of the Report to the current statutory provisions relating to the use of emulsifiers and stabilisers in food.

The appendix should not be regarded as a legal instrument

The Minister of Agriculture, Fisheries and Food and the Minister of Health, acting jointly, in exercise of the powers conferred on them by sections four, seven and one hundred and twenty-three of the Food and Drugs Act, 1955**(a)**, and of all other powers enabling them in that behalf, having consulted with such organisations as appear to them to be representative of interests substantially affected by these regulations and having referred proposals for these regulations to the Food Hygiene Advisory Council in accordance with section eighty-two of the said Act (insofar as the regulations relate to the labelling, marking, advertising or description of food), hereby make the following regulations:—

Citation and commencement

1. These regulations may be cited as the Emulsifiers and Stabilisers in Food Regulations, 1962; and shall come into operation on the 16th day of July 1962, except that paragraph (2) of regulation 5 and regulation 6 shall come into operation on the 14th day of January 1963.

Interpretation

2.—(1) In these regulations, unless the context otherwise requires—

"the Act" means the Food and Drugs Act, 1965;

"bread" means bread intended for sale for human consumption and includes the following, and any part of any of the following, that is to say, rolls, baps, fancy loaves, milk loaves, malt loaves and fruit loaves;

"cellulose ethers" means any compound obtained by replacing the hydrogen atoms in the hydroxyl groups in cellulose by one or more of the following substituent groups—methyl, ethyl, hydroxy-ethyl, hydroxy-propyl;

"complete glycerol esters" means any compound formed by completely esterifying the hydroxyl groups of glycerol with either—

(*a*) a mixture of a single fatty acid and acetic acid; or

(*b*) a mixture of fatty acids and lactic acid; or

(*c*) a mixture of fatty acids and phosphoric acid; or

(*d*) a mixture of fatty acids and diacetyl tartaric acid;

"cream" means that part of milk rich in fat which has been separated by skimming or otherwise and is intended for sale for human consumption;

(a) 4 & 5 Eliz. 2. c. 16.

"emulsifier" and "stabiliser" mean respectively any substance, other than a natural food substance, which is capable—

(*a*) in the case of an emulsifier, of aiding the formation of, and

(*b*) in the case of a stabiliser, of maintaining,

the uniform dispersion of two or more immiscible substances, but do not in either case include agar, alginic acid, calcium alginate, sodium alginate, carrageen, edible gums, dextrin, pectin, calcium pectate, sodium pectate, calcium chloride, calcium lactate, lecithin, quillaia, proteins (whether hydrolysed or not), calcium caseinate, sodium caseinate, starches (whether modified or not), malt extract, sorbitol, any substance inasmuch as its use is permitted by the Public Health (Preservatives etc. in Food) Regulations, 1925 to 1958**(a)**, the Colouring Matter in Food Regulations, 1957**(b)**, or the Antioxidant in Food Regulations, 1958**(c)**, or the sodium or potassium salts of any of the following, that is to say, acetic acid, carbonic acid, citric acid, lactic acid, malic acid, phosphoric acid, polyphosphoric acid or tartaric acid;

"flour" means the product intended for sale for human consumption which is derived from, or separated during, the milling or grinding of wheat, whether or not any of the wheat has been malted or subjected to any process and whether or not the product contains enzyme active preparations, and includes meal but does not include separated wheat offals, separated wheat germ or semolina;

"food" includes—

(*a*) cream and any food containing milk, and

(*b*) drink, chewing gum and other products of a like nature and use, and articles and substances used as ingredients in the preparation of food or drink or of such products;

but does not include—

(i) water, live animals or birds, or

(ii) articles or substances used only as drugs;

and except as respects regulations 5 and 6 hereof, the expression means food intended for sale for human consumption;

"food and drugs authority" has the meaning assigned to it by section 83 of the Act;

"inter-esterification" means the combination of a number of molecules of ricinoleic acid by the linking, with the elimination of water, of the hydroxyl group of one molecule with the carboxyl group of another molecule; and "inter-esterified" shall be construed accordingly;

"natural food substance" means any substance, suitable for use as food and commonly used as food, which is wholly a natural product, whether or not that substance has been subjected to any process or treatment;

(a) *See* Rev. VIII, p. 95 and also S.I. 1953/1820, 1957/1066, 1958/1319, 2167 (1953 I, p. 818; 1957 I, p. 996; 1958 I, pp. 1175, 1177).

(b) S.I. 1957/1066 (1957 I, p. 996).

(c) S.I. 1958/1454 (1958 I, p. 1161).

"partial polyglycerol esters" means any compound formed by incompletely esterifying the hydroxyl groups of condensed glycerol, which has been formed by causing glycerol to react with itself with the elimination of water, with either—

(*a*) any single fatty acid; or

(*b*) any mixture of fatty acids; or

(*c*) dimerised fatty acids of soya bean oil; or

(*d*) inter-esterified fatty acids of castor oil;

"partial glycerol esters" means any compound formed by incompletely esterifying the hydroxyl groups of glycerol with either—

(*a*) any single fatty acid; or

(*b*) any mixture of fatty acids; or

(*c*) any mixture of fatty acids with one of the following organic acids—acetic acid, lactic acid, citric acid, tartaric acid, diacetyl tartaric acid or hydroxystearic acid;

in which the proportion of sodium salt, if any, of any fatty acid present does not exceed two per centum (estimated by weight) of the partial glycerol ester;

"permitted emulsifier" means any emulsifier specified in the First Schedule to these regulations;

"permitted stabiliser" means any stabiliser specified in the First Schedule to these regulations;

"preparation", in relation to food, includes manufacture and any form of treatment;

"propylene glycol esters" means any compound formed by completely or incompletely esterifying the hydroxyl groups of propylene glycol with either—

(*a*) any single fatty acid; or

(*b*) any mixture of fatty acids; or

(*c*) any mixture of fatty acids and lactic acid; or

(*d*) alginic acid;

"reconstituted cream" means a substance which, not being cream, resembles cream in appearance and contains no ingredient not derived from milk, except—

(*a*) water, or

(*b*) ingredients (not added fraudulently to increase bulk, weight or measure, or conceal inferior quality) which may lawfully be contained in a substance sold for human consumption as cream;

and is intended for sale for human consumption;

"sell" includes offer or expose for sale or have in possession for sale; and "sale" shall be construed accordingly;

"thickening substance" means sucrate of lime, gelatine, starch paste or any other substance which, when added to cream or reconstituted cream, is capable of increasing its viscosity, but does not include cane sugar or beet sugar;

AND other expressions have the same meaning as in the Act.

(2) For the purposes of these regulations, the supply of food, otherwise than by sale, at, in or from any place where food is supplied in the course of a business shall be deemed to be a sale of that food.

(3) These regulations shall not apply to any emulsifier or stabiliser, or to any food containing any emulsifier or stabiliser, intended for exportation to any place outside the United Kingdom.

(4) The Public Health (Preservatives etc. in Food) Regulations, 1925 to 1958, shall not apply in relation to any emulsifier or stabiliser or as respects any emulsifier or stabiliser in food.

(5) Save for the provisions of regulation 11 hereof, any reference in these regulations to any other regulations shall be construed as a reference to those regulations as amended by any subsequent regulations, and if any regulations referred to in these regulations are replaced by any subsequent regulations the reference shall be construed as a reference to those subsequent regulations.

(6) The Interpretation Act, 1889**(a)**, shall apply to the interpretation of these regulations as it applies to the interpretation of an Act of Parliament.

Sale etc. of food containing emulsifiers or stabilisers

3.—(1) Subject to the provisions of this regulation, no food shall contain any emulsifier or any stabiliser which is not a permitted emulsifier or a permitted stabiliser.

(2) No flour, intended for sale as such, shall contain any emulsifier or any stabiliser.

(3) No bread shall contain any emulsifier or any stabiliser other than stearyl tartrate or partial glycerol esters.

(4) No person shall sell, consign or deliver, or import into England and Wales, any food which does not comply with this regulation.

(5) This regulation shall not apply in relation to any food containing any emulsifier or any stabiliser—

(*a*) inasmuch as that emulsifier or that stabiliser is naturally present in that food;

(*b*) by reason not of the use of that emulsifier or that stabiliser as an ingredient in that food but only of the use during the preparation of that food of a tin greasing emulsion containing that emulsifier or that stabiliser.

Sale etc. of cream and reconstituted cream

4.—(1) No cream or reconstituted cream shall contain any thickening substance.

(2) No person shall sell, consign or deliver, or import into England and Wales, any cream or reconstituted cream which does not comply with this regulation.

Sale, advertising and labelling of emulsifiers and stabilisers

5.—(1) No person shall sell or advertise for sale, with a view to its use in the preparation of food for human consumption, any emulsifier or any stabiliser other than a permitted emulsifier or a permitted stabiliser.

(a) 52 & 53 Vict. c. 63.

(2) No person shall sell any permitted emulsifier or permitted stabiliser with a view to its use in the preparation of food for human consumption except in a container bearing a label in accordance with the provisions of the Second Schedule to these regulations.

6.—(1) No person shall, with a view to the use of any permitted emulsifier or permitted stabiliser in the preparation of food for human consumption,—

(*a*) give or display with any permitted emulsifier or permitted stabiliser sold by him any label, whether attached to or printed on the wrapper or container or not, or

(*b*) publish, or be party to the publication of, any advertisement of any permitted emulsifier or permitted stabiliser for sale,

which bears or includes any statement which is calculated to lead to the use of that emulsifier or stabiliser in a manner contrary to these regulations.

(2) No person shall, with a view to the use of any permitted emulsifier or permitted stabiliser in the preparation of food for human consumption,—

(*a*) give or display with any permitted emulsifier or permitted stabiliser sold by him any label, whether attached to or printed on the wrapper or container or not, or

(*b*) publish, or be party to the publication of, any advertisement of any permitted emulsifier or permitted stabiliser for sale,

which bears or includes any statement which is calculated to imply either directly or by ambiguity, omission or inference that that emulsifier or stabiliser is a substitute for fat or eggs.

Prohibition of sale or advertisement of any thickening substance for cream or reconstituted cream

7.—(1) No person shall sell any substance as a thickening substance for cream or reconstituted cream.

(2) No person shall—

(*a*) give or display with any substance sold by him any label, whether attached to or printed on the wrapper or container or not, or

(*b*) publish, or be party to the publication of, any advertisement of any substance for sale,

which bears or includes any description or statement which is calculated to lead to its being used as a thickening substance for cream or reconstituted cream.

Condemnation of food containing any prohibited emulsifier or stabiliser

8. Where any food is certified by a public analyst as being food which it is an offence against regulation 3 hereof to sell, consign or deliver, or import into England and Wales, that food may be treated for the purpose of section 9 of the Act (under which food may be seized and destroyed on the order of a justice of the peace) as being unfit for human consumption.

Penalties, enforcement and defence for publisher of an advertisement

9.—(1) If any person contravenes or fails to comply with any of the foregoing provisions of these regulations he shall be guilty of an offence and shall be liable to a fine not exceeding one hundred pounds or to imprisonment for a term not exceeding three months, or to both, and, in the case of a continuing offence, to a further fine not exceeding five pounds for each day during which the offence continues after conviction.

(2) Each food and drugs authority shall enforce and execute such provisions in their area:

Provided that each port health authority shall enforce and execute in their district the provisions of regulations 3 and 4 hereof insofar as they relate to importation.

(3) In any proceedings for an offence against paragraph (1) of regulation 5, regulation 6 or 7 hereof in relation to the publication of an advertisement, it shall be a defence for the defendant to prove that, being a person whose business it is to publish, or arrange for the publication of, advertisements, he received the advertisement for publication in the ordinary course of business.

(4) The requirements of subsection (3) of section 109 of the Act (which requires notice to be given to the Minister of Agriculture, Fisheries and Food of intention to institute proceedings for an offence against any provisions of these regulations relating to labelling, marking or advertising) shall not apply as respects any proceedings instituted by a council for an offence against any such provisions of these regulations.

Application of various sections of the Act

10.—(1) Subsections (3) and (4) of section 108 (which relates to prosecutions), subsections (1), (2) and (3) of section 110 (which relates to evidence of analysis), sections 112 (which relates to the power of a court to require analysis by the Government Chemist) and 113 (which relates to a contravention due to some person other than the person charged) subsection (2) of section 115 (which relates to the conditions under which a warranty may be pleaded as a defence) and section 116 (which relates to offences in relation to warranties and certificates of analysis) of the Act shall apply for the purposes of these regulations as if references therein to proceedings, or a prosecution, under or taken or brought under the Act included references to proceedings, or a prosecution as the case may be, taken or brought for an offence under these regulations and as if the reference in the said section 112 to the said subsection (4) of section 108 included a reference to that subsection as applied by these regulations.

(2) Paragraph (*b*) of the proviso to subsection (1) of section 108 of the Act shall apply for the purposes of these regulations as if the reference therein to section 116 of the Act included a reference to that section as applied by these regulations.

Amendment of the Public Health (Preservatives etc. in Food) Regulations, 1925 to 1958

11. The Public Health (Preservatives etc. in Food) Regulations, 1925, as amended, shall be further amended by deleting from paragraph (1) of regulation 2 thereof the definition of thickening substance, by deleting paragraph (3) of

regulation 4, paragraph (3) of regulation 5 and paragraph (2) of regulation 11 and by deleting from regulation 12 thereof the words "or thickening substance", but without prejudice to any proceedings begun or action taken in pursuance of any of those regulations.

Regulation 2 (1)

THE FIRST SCHEDULE

Permitted Emulsifiers and Permitted Stabilisers

Stearyl tartrate.
Complete glycerol esters.
Partial glycerol esters.
Partial polyglycerol esters.
Propylene glycol esters.
Monostearin sodium sulphoacetate.
Sorbitan esters of fatty acids and their polyoxyethylene derivatives.
Cellulose ethers.
Sodium carboxymethyl cellulose.
Brominated edible vegetable oils.

Regulation 5 (2)

THE SECOND SCHEDULE

Labelling of Permitted Emulsifiers and Permitted Stabilisers

1. Each container to which regulation 5 (2) relates shall bear a label on which is printed a true statement of the chemical nature of the emulsifier or stabiliser and a declaration that it is of the necessary purity for use in food.

2. Such statement and declaration shall be printed distinctly and legibly in dark block type upon a light-coloured ground or in light block type upon a dark-coloured ground, the type being not less than one-eighth of an inch in height, within a surrounding line and no other matter shall be printed within such surrounding line. The type shall be of uniform size and colour and the ground within the said surrounding line shall be of uniform colour.

3. Such label shall be securely affixed to, or be part of, the wrapper or container and in any case shall be so placed as to be clearly visible and shall either be part of any main label or a separte label placed in close proximity thereto.

PROPOSED SPECIFICATIONS FOR PERMITTED EMULSIFIERS AND STABILISERS

The specifications apply to emulsifiers/stabilisers prior to any subsequent mixing or dilution with other ingredients. In addition to the requirements below, permitted emulsifiers and stabilisers shall not contain impurities in amounts greater than are to be found in good manufacturing practice. Arsenic and lead limits shall comply with The Arsenic in Food Regulations 1959/60 and The Lead in Food Regulations, 1961. Requirements for odour, taste and precise viscosity are not considered important for the purposes of these specifications.

NA = None available.
FCC = Food Chemicals Codex, 1966.
BP = British Pharmacopoeia, 1968.
BPC = British Pharmaceutical Codex, 1968.
FAO/WHO = Seventh Report of the Joint FAO/WHO Expert Committee on Food Additives (Rome, 1964).

Emulsifier/Stabiliser	Official Specification	Other requirements
1 Agar	FCC p. 17	—
2 Alginic Acid	FCC p. 20	—
3 Calcium Alginate	FCC p. 101	—
4 Sodium Alginate	FCC p. 600	—
5 Carrageenan (*Synonym:* Carrageen)	FCC p. 156	—
6 Acacia (*Synonym:* Gum Arabic)	FCC p. 7	—
7 Karaya Gum	FCC p. 359	—
8 Tragacanth	FCC p. 698	—
9 Locust Bean Gum (*Synonym:* Carob gum)	FCC p. 392	—
10 Ghatti Gum	NA	—
11 Guar Gum (*Synonym:* Guar Flour)	FCC p. 315	—
12 Pectin	National Formulary, 12th Edition; but delete "to the convenient '150 jelly grade' "	—
13 Calcium Pectate	NA	—
14 Sodium Pectate	NA	—
15 Lecithin	FCC p. 376	—

Emulsifier/Stabiliser	Official Specification	Other requirements
16 Quillaia	BP p. 854	Shall be used only in the form of Quillaia BP, Powdered Quillaia BP or their aqueous, ethanolic or isopropanolic extracts.
17 Calcium Caseinate	NA	—
18 Sodium Caseinate	NA	—
19 Modified Food Starches	See Attachment 1	—
20 Oxidatively Polymerised Soya Bean Oil	See Attachment 2	—
21 Stearyl Tartrate	See Attachment 3	—
22 Mono- and Diglycerides (of fatty acids)	FCC p. 452 but excluding "Residue on ignition".	(*a*) May contain up to 6 per cent by weight of sodium and/or potassium salts of fatty acids [calculated as sodium oleate $C_{18}H_{33}NaO_2$]. (*b*) The hydroxyl value of the free and combined fatty acids of mono- and diglycerides used in bread shall not exceed 2.
23 Acetylated Monoglycerides (*Synonym:* Acetoglycerides)	FCC p. 15	—
24 Lactated Mono-Diglycerides (*Synonym:* Lactoglycerides)	FCC p. 362	(*a*) Shall contain not less than 95 per cent by weight of total esters. (*b*) Shall contain from 5 to 30 per cent by weight of combined lactic acid. (*c*) Acid value shall not exceed 6 mg KOH per g.
25 Tartaric Acid Glycerides	NA	—
26 Diacetyl Tartaric Acid Esters of Mono- and Diglycerides	First Supplement to FCC, p. 4. Delete requirements for "Acid value" and "Saponification value."	—
27 Emulsifier YN	See Attachment 4	—
28 Polyglycerol Esters of Fatty Acids	See Attachment 5	—
29 Polyglycerol Esters of Polycondensed (interesterified) Fatty Acids from Castor Oil	See Attachment 6	—
30 Propylene Glycol Esters of Fatty Acids	See Attachment 7	—

Emulsifier/Stabiliser	Official Specification	Other requirements
31 Propylene Glycol Alginate	FCC p. 565	In the "Procedure" (FCC p. 719) line 15, substitute a heating period of 3 hours instead of 2 hours.
32 Sorbitan Monostearate	FCC p. 655	—
33 Sorbitan Tristearate	FAO/WHO p. 108	—
34 Sorbitan Monopalmitate	FAO/WHO p. 102	—
35 Sorbitan Monolaurate	BPC p. 770	—
36 Sorbitan Mono-oleate	BPC p. 771	—
37 Polysorbate 20 [*Synonym:* Polyoxyethylene (20) Sorbitan Monolaurate]	FCC p. 525	—
38 Polyoxyethylene (20) Sorbitan Monopalmitate [*Synonym:* Polysorbate 40]	FAO/WHO p. 135	—
39 Polysorbate 60 [*Synonym:* Polyoxyethylene (20) Sorbitan Monostearate]	FCC p. 526	—
40 Polysorbate 65 [*Synonym:* Polyoxyethylene (20) Sorbitan Tristearate]	FCC p. 528	—
41 Polysorbate 80 [*Synonym:* Polyoxyethylene (20) Sorbitan Mono-oleate]	FCC p. 529	—
42 Methylcellulose	FCC p. 432	—
43 Ethylcellulose	FCC p. 254	—
44 Methyl Ethylcellulose	FCC p. 436	—
45 Hydroxypropyl Cellulose	FCC p. 333	—
46 Hydroxypropyl Methylcellulose	FCC p. 335	—
47 Sodium Carboxymethyl Cellulose	FCC p. 610. Shall contain not less than 99·0 per cent sodium carboxymethyl cellulose by weight.	—
48 Dioctyl Sodium Sulphosuccinate	FCC p. 238	—
49 Microcrystalline Cellulose	BPC p. 135	Shall contain not more than 200 mg of diethyl ether extractable matter per kg.

PROPOSED SPECIFICATIONS FOR MODIFIED FOOD STARCHES

A. **General requirements** (applicable to all modified food starches).

(*a*) *Preparation.* Modified Starches shall be prepared from Starch BP by one of the methods outlined in section B. Bleaching (modification B1) or acid-thinning may be used in conjunction with each of the modifications listed under B3 to B8 inclusive. Modified Starches may be gelatinised after any modification.

(*b*) *Description.* Modified Starches shall be white amorphous powders or granules.

(*c*) *Ash content.* Maximum 2 per cent by weight.

(*d*) *pH* (aqueous suspension). 5 to 8.

(*e*) *Sulphur dioxide.* Maximum 100 mg per kg.

B. **Specific requirements**

(1) BLEACHED STARCH

(*a*) *Synonym.* Lightly bleached starch.

(*b*) *Preparation.* Bleached Starch shall be prepared by treating an aqueous suspension of starch at below gelatinising temperatures, with one of the following agents:

Hydrogen peroxide and/or *peracetic acid* (maximum 0·45 per cent active oxygen by weight of starch).

Sodium hypochlorite (maximum 0·82 per cent available chlorine by weight of starch).

Sodium chlorite (maximum 0·5 per cent by weight of starch).

(*c*) *Residual hydrogen peroxide* and/or *peracetic acid.* Negative (Section C, Method 1).

(2) OXIDISED STARCH

(*a*) *Preparation.* Oxidised Starch shall be prepared by treating an aqueous suspension of starch, at below gelatinising temperatures, with sodium hypochlorite and alkali.

(*b*) *Carboxyl groups.* Maximum 1 per cent by weight. (Section C, Method 2).

(3) DI-STARCH PHOSPHATE

(*a*) *Synonym.* Phosphate cross-bonded starch ester.

(*b*) *Preparation.* Di-Starch Phosphate shall be prepared by treating an alkaline aqueous suspension of starch, at below gelatinising temperatures, with sodium trimetaphosphate or phosphoryl chloride.

(*c*) *Phosphate.* Maximum 0·04 per cent by weight calculated as elemental phosphorus.

(4) PHOSPHATED DI-STARCH PHOSPHATE

(*a*) *Synonym.* Phosphate cross-bonded starch phosphate ester.

(*b*) *Preparation.* Phosphated di-Starch Phosphate shall be prepared by treating dry starch with sodium tripolyphophate followed by treatment of an alkaline aqueous suspension of the resultant product, at below gelatinising temperatures, with sodium trimetaphosphate.

(*c*) *Phosphate.* Maximum 0·4 per cent by weight calculated as elemental phosphorus.

(5) STARCH ACETATE

(*a*) *Preparation.* Starch Acetate shall be prepared by treating an alkaline aqueous suspension of starch, at below gelatinising temperatures, with acetic anhydride or vinyl acetate.

(*b*) *Acetyl groups.* Maximum 2·5 per cent by weight.

(6) DI-STARCH GLYCEROL

(*a*) *Synonym.* Starch ether.

(*b*) *Preparation.* Di-Starch Glycerol shall be prepared by treating an alkaline aqueous suspension of starch, at below gelatinising temperatures, with up to 0·3 per cent epichlorhydrin by weight of starch.

(*c*) *Total chlorhydrins.* Maximum 5 mg per kg. (Section C, Method 3).

(7) ACETYLATED DI-STARCH GLYCEROL

(*a*) *Synonym.* Esterified starch ether.

(*b*) *Preparation.* Acetylated di-Starch Glycerol shall be prepared by treating an alkaline aqueous suspension of starch, at below gelatinising temperatures, with up to 0·3 per cent epichlorhydrin by weight of starch followed by acetic anhydride.

(*c*) *Total chlorhydrins.* Maximum 5 mg per kg (Section C, Method 3).

(*d*) *Acetyl groups.* Maximum 2·5 per cent by weight.

(8) ACETYLATED DI-STARCH ADIPATE

(*a*) *Preparation.* Acetylated di-Starch Adipate shall be prepared by treating an alkaline aqueous suspension of starch, at below gelatinising temperatures, with acetic anhydride and up to 0·12 per cent adipic anhydride by weight of starch.

(*b*) *Acetyl groups.* Maximum 2·5 per cent by weight.

C. **Analytical methods**

Method 1. Residual hydrogen peroxide and/or peracetic acid

Add 50 g starch to 245 ml water. Shake for ½ hour. Filter. Place 100 ml of filtrate in a stoppered flask. Add 200 ml water, 20 ml of 5 per cent w/v sulphuric acid and 10 ml of freshly prepared 20 per cent w/v potassium iodide solution. Mix and allow to stand in a dark cool place for 10 minutes. Add starch indicator and titrate with 0·02N sodium thiosulphate solution (T). Carry out a "blank" determination simultaneously (B). The test is negative if T is not greater than B.

Method 2. Determination of the Carboxyl Content of Oxidised Starches. (Paste Titration Method)
M. F. Matisson and K. A. Legendre.
Analytical Chemistry, 1952, *24*, 1942.

Method 3. Steam distillation followed by gas/liquid chromatography e.g. Isolation and Determination of Chlorohydrins in Foods fumigated with Ethylene Oxide or with Propylene Oxide. E. P. Ragelis, B. S. Fisher, B. A. Kimeck and C. Johnson, *Journal of the Association of Official Agricultural Chemists*, 1968, *51*, 709.

ATTACHMENT 2

PROPOSED SPECIFICATION FOR OXIDATIVELY POLYMERISED SOYA BEAN OIL

Composition.	Oxidatively polymerised soya bean oil shall be the product obtained by blowing air into edible soya bean oil at a temperature not exceeding 250°C.
Description.	Oxidatively polymerised soya bean oil shall be a highly viscous liquid at 25°C.
Refractive index.	$\left(n_D^{40^\circ C}\right)$: 1·475–1·485
Iodine value.	75–85 (Wijs)
Hydroxyl value.	30–70
Saponification value.	220
Combined oxidised fatty acids.	maximum 30 per cent by weight (Analytical Method 1)
Urea non-adduct content.	maximum 40 per cent by weight (Analytical Method 2)
Acid value.	maximum 6 mg KOH per g.

Analytical Methods

1. Method II.D.12
   Standard Methods of the Oils and Fats Section of the International Union of Pure and Applied Chemistry, 5th Edition (Butterworths, 1966).
2. Urea Adduction, page 473 of paper by
   D. Firestone, S. Nesheim and W. Horwitz, *Journal of the Association of Official Agricultural Chemists*, 1961, *44*, 465–474.

ATTACHMENT 3

PROPOSED SPECIFICATION FOR STEARYL TARTRATE

Synonym.	Cetyl stearyl tartrate.
Composition.	Stearyl tartrate shall be the product of the esterification of food-grade tartaric acid with commercial food-grade stearyl alcohol. It shall consist mainly of di-ester with minor amounts of monoester and unchanged starting materials.
Description.	Stearyl tartrate shall be a cream-coloured unctuous solid at 25°C.
Total ester content.	Minimum 90 per cent by weight.
Ester value.	163–180 mg KOH per g.
Unsaponifiable matter.	77–83 per cent by weight.
Melting range.	67–77°C.
Acid value.	Maximum 6 mg KOH per g.
Iodine value.	Maximum 4. (Wijs).

[*Acknowledgement.* The above specification is based mainly on a draft specification provided by The British Standards Institution.]

ATTACHMENT 4

PROPOSED SPECIFICATION FOR EMULSIFIER YN

1. *Composition*

   Emulsifier YN shall consist essentially of a mixture of the ammonium compounds of phosphatidic acids derived from partially-hardened rapeseed oil together with unreacted triglycerides from partially-hardened rapeseed oil.

2. *Description*

   Emulsifier YN shall be an unctuous semi-solid at 25°C.

3. *Petrol-Insoluble Matter*

   Emulsifier YN shall yield not more than 2·5 per cent by weight of matter insoluble in 40–60 petroleum ether [Analytical Method 8(i)].

4. *Inorganic Petrol-Insoluble Matter*

   Emulsifier YN shall yield not more than 0·2 per cent by weight of inorganic matter insoluble in 40–60 petroleum ether [Analytical Method 8(ii)].

5. *Neutrality*

The pH value of an aqueous extract derived from melted Emulsifier YN shall lie within the range 6·0 to 8·0.

6. *Phosphorus*

Emulsifier YN shall contain from 3·0 to 3·4 per cent by weight of phosphorus.

7. *Ammonium Nitrogen*

Emulsifier YN shall contain from 1·2 to 1·5 per cent by weight of ammonium nitrogen.

8. *Analytical Methods*

(i) Method II. C. 2 (using light petroleum).
Standard Methods of the Oils and Fats Section of the International Union of Pure and Applied Chemistry, 5th Edition (Butterworths, 1966).
(ii) Ash the petrol-insoluble matter from (i) at 550°C to constant weight.

ATTACHMENT 5

PROPOSED SPECIFICATION FOR POLYGLYCEROL ESTERS OF FATTY ACIDS

Synonym.	Glyceran esters of fatty acids.
Composition of esters.	Polyglycerol esters of fatty acids shall be the product of the esterification of polyglycerol (see below) with food fats or with the fatty acids of food fats (see below). They may contain up to 6 per cent by weight of sodium and/or potassium salts of fatty acids (calculated as sodium oleate, $C_{18}H_{33}Na\,O_2$).
Composition of polyglycerol.	The polyglycerol moiety shall be predominantly di-, tri- and tetra-glycerol and shall not contain polymers larger than hexaglycerol. (Analytical Method 1).
Composition of food fats or the fatty acids of food fats.	The fatty acids moiety shall lie between C_{12} to C_{24} straight-chain fatty acids (excluding hydroxy-acids) and shall melt betwen 35°C and 60°C.
Description.	Polyglycerol esters of fatty acids shall be cream-coloured unctuous solids or semi-solids at 25°C.
Total ester content.	minimum 90 per cent by weight, on a "soap"-free basis.
Acid value.	maximum 6 mg KOH per g.

Analytical Method

(1) The composition of the polyglycerol moiety shall be determined by thin layer chromatography:
Dallas & Stewart,
Analyst, 1967, *92*, 634.

ATTACHMENT 6

PROPOSED SPECIFICATION FOR POLYGLYCEROL ESTER OF THE POLYCONDENSED FATTY ACIDS FROM CASTOR OIL

Composition of the product.	The product shall consist mainly of a complex mixture of the partial esters and ethers of polyglycerol (see below) with linearly interesterified (polycondensed) castor oil fatty acids. The polycondensed castor oil fatty acids shall be prepared by condensation in the absence of oxygen and have an average of about 5 fatty acid residues per molecule.
Composition of polyglycerol.	The polyglycerol moiety shall be predominantly di-, tri- and tetra-glycerol and shall not contain polymers larger than hexaglycerol. (Analytical Method 1).
Description.	The polyglycerol ester of the polycondensed fatty acids from castor oil shall be a highly viscous liquid at 25°C.
Refractive index.	$\left(n_{D}^{65^\circ C}\right)$ 1·4630–1·4665.
Hydroxyl value.	81–94.
Iodine value.	72–103 (Wijs).
Acid value.	maximum 6 mg KOH per g.

Analytical Method

(1) The composition of the polyglycerol moiety shall be determined by thin-layer chromatography.
Dallas & Stewart.
Analyst, 1967, *92*, 634.

ATTACHMENT 7

PROPOSED SPECIFICATION FOR PROPYLENE GLYCOL ESTERS OF FATTY ACIDS

Composition.	Propylene glycol esters of fatty acids shall consist mainly of mixtures of 1,2-propanediol mono- and di-esters of C_8–C_{24} straight-chain fatty acids (excluding hydroxy-acids) of food fats. Acids, other than fatty acids, and alcohols, other than 1,2-propanediol, shall be absent.
Uncombined 1,2-propanediol.	maximum 5 per cent by weight.
Acid value.	Maximum 6 mg KOH per g.

TABLE OF RECOMMENDATIONS ON INDIVIDUAL SUBSTANCES

Code

A = acceptable
B = provisionally acceptable
C = possibly toxic
D = probably toxic
E = data inadequate

R = recommended for inclusion on revised permitted list
‡ = acceptable also for use in whipped cream
† = currently permitted in bread
* = acceptable for use in bread in revised list
X = rejected

A. *Currently "defined-out" or excluded from control in the 1962 Regulations*

Substance	PSC Classification	FACC Decision	Notes
Agar	A	R	
Alginic acid	A	R	
Calcium alginate	A	R	
Sodium alginate	A	R‡	
Carrageen	A	R	
Edible gums:			
Acacia	A	R	
Karaya	A	R	
Tragacanth	A	R	
Carob	A	R	
Ghatti	B	R	
Guar	B	R	
Dextrins	A	Define out	
Pectin	A	R	
Calcium pectate	A	R	
Sodium pectate	A	R	
Calcium chloride	A		Further Classes Report 1968
Calcium lactate	A		Further Classes Report 1968
†**Lecithin**	—	R*	
Quillaia	B	R	Soft drinks only—max. 200 ppm
†**Proteins**, †**protein concentrates and** protein hydrolysates	—	Define out	Natural food substance
Calcium caseinate	—	R	
Sodium caseinate	—	R	
Starches (whether modified or not)			
Natural and acid-thinned	A	Define out	
Bleached (with chlorite, hypochlorite, hydrogen peroxide, peracetic acid)	A	R	
with potassium permanganate	E	X	
Hypochlorite oxidised	A	R	
Di-starch phosphate (tri-metaphosphate modified)	A	R	
Di-starch phosphate (phosphoryl chloride modified)	B	R	
Phosphated di-starch phosphate	B	R	
Di-starch glycerol	B	R	

Substance	PSC Classification	FACC Decision	Notes
Starch acetates	B	R	
Acetylated di-starch glycerol	B	R	
Acetylated di-starch adipate	B	R	
Sodium carboxymethyl di-starch glycerol	C	X	
Acetylated di-starch phosphate	E	X	
Starch sodium succinate	E	X	
Starch sodium octenyl succinate	E	X	
Starch aluminium octenyl succinate	E	X	Not an emulsifier
Hydroxypropyl starch	E	X	
Enzyme modified starch	E	X	
†Malt extract	—	Define out	Natural food substance
Sorbitol	A		Further Classes Report 1968
Sodium or potassium salts of:			
Acetic acid	A		Further Classes Report 1968
Carbonic acid	A		
Citric acid	A		
Lactic acid	A		
Malic acid	A		
Phosphoric acid	A		
Polyphosphoric acid	A		
Tartaric acid	A		
Tin-greasing emulsifiers			
Release agents	A & E		Further Classes Report 1968
Oxidatively polymerised soya bean oil	B	R	For tin greasing only—max. 50 ppm in any food.
Other "blown" oils	E	X	

B. Currently permitted in the First Schedule to the 1962 Regulations

Substance	PSC Classification	FACC Decision	Notes
†Stearyl tartrate	A*	R*	
Complete and †partial glycerol esters:			
†Mono- and di-glycerides of fatty acids (excluding hydroxystearic)	A*	R*	
†Mono- and di-glycerides of fatty acids (with hydroxystearic)	B	R	
†Acetoglycerides	A	R	
†Lactoglycerides	B	R	
†Citroglycerides	E	X	
†Tartaric acid glycerides	A	R	
†Diacetyltartaric acid glycerides	B*	R*	
Phosphoric acid glycerides	—	X	No data submitted
Emulsifier YN	B	R	
Partial polyglycerol esters			
Polyglycerol fatty acid esters	A	R	

Substance	PSC Classification	FACC Decision	Notes
Polyglycerol esters of dimerised fatty acids of soya bean oil	E	X	
Polyglycerol esters of polycondensed (inter-esterified) fatty acids of castor oil	B	R	
Propylene glycol esters			
Propylene glycol esters of fatty acids	B	R	
Propylene glycol esters of fatty acids and lactic acid	E	X	
Propylene glycol alginates	B	R	
Monostearin sodium sulphoacetate	—	X	No demand for use in U.K.
Sorbitan esters of fatty acids			
Sorbitan monostearate	B	R	In certain foods only
Sorbitan tristearate	B	R	
Sorbitan monopalmitate	B	R	
Sorbitan monolaurate	B	R	
Sorbitan monooleate	B	R	
Polyoxyethylene sorbitan esters of fatty acids			
Polyoxyethylene (20) sorbitan			
—monolaurate	A	R	In certain foods only
—monopalmitate	A	R	
—monostearate	A	R	
—tristearate	B	R	
—monooleate	B	R	
Cellulose ethers			
(methyl, ethyl, hydroxyethyl and hydroxypropyl derivatives of cellulose)	A	R	
Sodium carboxymethyl cellulose	A	R‡	
Brominated edible vegetable oils	D	X	

C. Substances submitted for inclusion in revised Regulations

Substance	PSC Classification	FACC Decision	Notes
Sodium monostearyl fumarate	E	X	
Sucrose esters of fatty acids and sucrogylcerides	E	X	
Polyoxyethylene stearates			
Polyoxyethylene (8) stearate	A	X	
Polyoxyethylene (40) stearate	B	X	
Dioctyl sodium sulphosuccinate	A	R	In certain foods only
Microcrystalline cellulose	A	R	
Octadecylamine	B	—	No recommendation
Octadecylamine acetate	B	—	No recommendation
Cetomacrogol 1000	—	X	Toxicological evidence incomplete and need in U.K. not accepted.
Solvitose gum OH 40	—	X	
Sodium carboxymethyl galactomannose	—	X	
Pentaerythritol stearate	—	X	
Stearyl lactylic acid	—	X	
Calcium stearyl dilactylate	—	X	
Stearyl monoglyceride citrate	—	X	
Calcium sucrose phosphate	—	X	In development stage
Hydroxylated lecithin	—	X	No recommendation necessary

The Pharmacology Sub-Committee presented the following report and agreed that it should be incorporated as an annex to the Food Additives and Contaminants Committee's Report.

COMMITTEE ON MEDICAL ASPECTS OF FOOD POLICY

PHARMACOLOGY SUB-COMMITTEE

REPORT ON THE REVIEW OF THE EMULSIFIERS AND STABILISERS IN FOOD REGULATIONS, 1962

Introduction

1. We were asked by the Food Additives and Contaminants Committee to study the available toxicological information on certain emulsifiers and stabilisers, to point out where necessary the gaps in the evidence, and to give a clear recommendation as to which of the substances should and which should not be permitted for use in food.

Substances submitted

2. The following emulsifiers and stabilisers were submitted for our opinion under the descriptions below:

(*a*) *Permitted for use in food according to the current Regulations*
(*only those marked with an asterisk may at present be used in bread)

(i) Agar
(ii) Alginic acid, calcium alginate, sodium alginate
(iii) Carrageen
(iv) Edible gums (acacia, karaya, tragacanth, carob, ghatti and guar)
(v) Pectin, calcium pectate, sodium pectate
(vi) Quillaia
(vii) Modified starches (including dextrin)
(viii) *Stearyl tartrate
(ix) Emulsifier YN (ammonium phosphatides)
(x) *Commercial mono- and di-glycerides of fatty acids, including hydroxystearic acid
(xi) *Acetoglycerides
(xii) *Lactoglycerides
(xiii) *Citroglycerides
(xiv) *Tartaric acid glycerides
(xv) *Diacetyl tartaric acid esters of mono- and di-glycerides
(xvi) Polyglycerol esters of fatty acids
(xvii) Polyglycerol esters of dimerised fatty acids of soyabean oil
(xviii) Polyglycerol esters of interesterified fatty acids of castor oil
(xix) Propylene glycol esters of fatty acids
(xx) Propylene glycol esters of fatty acids and lactic acid

(xxi) Propylene glycol alginates
(xxii) Sorbitan esters of fatty acids
(xxiii) Polyoxyethylene sorbitan esters of fatty acids
(xxiv) Cellulose ethers
(xxv) Sodium carboxymethyl cellulose
(xxvi) Brominated edible vegetable oils
(xxvii) "Blown oils"—solely from their use as emulsifiers in tin-greasing emulsions

(*b*) *Not currently permitted for use in food*

(i) Sodium mono-stearyl fumarate
(ii) Sucrose esters of fatty acids and sucroglycerides
(iii) Polyoxyethylene stearates
(iv) Dioctyl sodium sulphosuccinate
(v) Microcrystalline cellulose
(vi) Octadecylamine acetate and octadecylamine

Specifications

3. A variety of substances can be covered by many of the above descriptions and frequently even a defined product is usually of heterogeneous composition. We were considerably handicapped by lack of information on the precise composition of many of the substances submitted and by inadequacy of the specifications given for them. A valid assessment can be made only if a given product as used in food can be shown to be identical with or, at least, very similar to the substance which has been subjected to toxicological tests. For the substances upon which we are prepared to make pronouncements about their use in food, specifications must be laid down and adhered to.

Surface-active agents

4. Little is known of the significance of the presence in the human alimentary tract of certain highly active agents, for example the sorbitan and polyoxyethylene sorbitan esters of fatty acids, dealt with in this Report. It has been established that such substances may exert profound effects on the morphology and biological behaviour of micro-organisms. Their physico-chemical properties may also modify the normal absorptive pattern and influence the enzymatic processes of the gastro-intestinal tract. There may be a need, in future, for special tests to be devised to elucidate these and other aspects such as cumulative effects from consumption in common foodstuffs.

Some emulsifiers of this kind have been used medically to influence the rate of absorption of nutrients (e.g. oils and fats) in pathological conditions and they often have a laxative effect. Although these considerations have caused us some concern we have been able to classify almost all these substances as acceptable or provisionally acceptable for use in food on the available evidence.

Detailed toxicological classifications

5. Our detailed toxicological classifications were based on the information received from various sources on individual substances. We found that for emulsifiers and stabilisers we needed to use only five of our usual six headings for classifying their acceptability as food additives.

These five were:

Group A. Additives that the available evidence suggests are acceptable for use in food.

Group B. Additives that on the available evidence may be regarded meantime as provisionally acceptable for use in food, but about which further information is necessary and which must be reviewed within a specified time.

Group C. Additives for which the available evidence suggests possible toxicity and which ought not to be allowed in food without further evidence establishing their acceptability.

Group D. Additives for which the available evidence suggests probable toxicity and which ought not to be allowed in food.

Group E. Additives for which the available evidence was inadequate to enable an opinion to be expressed as to their suitability for use in food.

We recommend that of the substances dealt with in the Report only those should be allowed in food which we have placed in Groups A and B. In classifying them as Group A or B we do not imply that all may be used freely. The nature and extent of any restrictions will have to be based upon criteria additional to the toxicological evidence, e.g., range of usage and likely combinations of several food additives. It should also be understood that any present classification is subject to review if new biological evidence is forthcoming.

Of those substances which have been proposed for use in bread *we are prepared to agree* that only stearyl tartrate, commercial mono- and di-glycerides of fatty acids excluding hydroxy fatty acids and diacetyl tartaric acid esters of mono- and di-glycerides should be permitted. Although we have classified polyoxyethylene (8) stearate as Group A, its use in bread may require consideration on other grounds.

We recommend that sorbitan—and polyoxyethylene sorbitan—esters of fatty acids and dioctyl sodium sulphosuccinate should not be permitted freely in view of our reservations set out in paragraph 4.

6. The remainder of this Report gives a brief summary of our appraisal of the evidence available to us with, where appropriate, an indication of further studies which are either necessary or desirable. We wish to point out that where chemically related substances have been given a different classification, this has in most instances been due to insufficient data relating to those placed in the lower category.

Group A

(i) *Agar*

Alginic acid, calcium alginate, sodium alginate

We would also be prepared to accept ammonium and potassium alginates as "group A" (WHO, 1964).

Carrageen

Although the biological information on this material is not extensive it has been used in food and pharmaceutical preparations for many years. (Nilson and Wagner, 1959; WHO, 1967 b).

Acacia, karaya, tragacanth, carob

Although the biological information on these materials is not extensive, they have been used in food and pharmaceutical preparations for many years and specifications are available (WHO, 1967 b).

Pectin, calcium pectate, sodium pectate

Provided suitable sources of pectin (e.g. citrus fruits and apples) are used in their manufacture we have no objection to the use of these substances (Fisher *et al*, 1966).

(ii) *Amylose and amylopectin starches* (fractionates from natural starch)

Acid-thinned starches (aqueous starch slurry treated with dilute acid)

White and yellow dextrins (dry starch heated in the presence of acid)

Bleached (lightly oxidised) starches
(using chlorite, hypochlorite, hydrogen peroxide, peracetic acid)

Hypochlorite oxidised starch

Di-starch phosphate (starch modified by treatment with sodium trimetaphosphate) [see also paragraph 7]

(iii) *Stearyl tartrate*

We agree that the toxicological data are adequate to enable us to accept the use of stearyl tartrate as a dough strengthening agent and bread "improver" at a level of 500 ppm by weight of flour. The toxicological information comprised bio-chemical studies, results of acute toxicity tests on several animal species, short-term feeding tests on rats and man and long-term feeding tests (including multigeneration studies) on the mouse and the rat (Schoenheimer and Hilgetag, 1934; Stetten and Schoenheimer, 1934; WHO, 1967 a).

(iv) *Commercial mono- and di-glycerides of fatty acids excluding hydroxy fatty acids*

We agree that these substances may be accepted because they are normal products of fat metabolism (WHO, 1964).

(v) *Acetoglycerides*

Tartaric acid glycerides

(vi) *Polyglycerol esters of fatty acids*

A large variety of products is comprised within the description "polyglycerol esters of fatty acids", each product being of heterogeneous composition. Two manufacturers have supplied detailed information on the composition and toxicology of their products. The toxicological evidence is sufficient for us to assess that no hazard is likely to arise from the use of the specified products in food at levels up to 3 per cent in fats, 1 per cent in chocolate, 0·5 per cent in ice-cream, and 2 per cent by weight of flour in cakes (Babayan *et al*, 1964; Bichel *et al*, 1964; WHO, 1967 a).

(vii) *Polyoxyethylene sorbitan esters of fatty acids*

We were informed that the polyoxyethylene sorbitan esters have been proposed by the manufacturers for use in a wide variety of foods including bread, as emulsifiers and de-foamers, often in conjunction with sorbitan esters of fatty acids. Usage in bread is not at present permitted in the U.K. Despite the close chemical relationship between various members of this group of compounds it has not been possible to assign to all of them the same classification because of the incompleteness of toxicological information for certain members of this group.

(*a*) *Polyoxyethylene (20) sorbitan monolaurate*

Adequate toxicological studies permit inclusion in Group A (Ewing and Tauber, 1965; WHO, 1964).

(*b*) *Polyoxyethylene (20) sorbitan monopalmitate*

Satisfactory results were available from a variety of acute, short-term and long-term oral feeding studies without any evidence of carcinogenicity. These enabled us to discount certain observations claiming to show that this substance might be capable of acting as a co-carcinogen under the particular condition of application to the skin of mice (Ewing and Tauber, 1965; WHO, 1964).

(*c*) *Polyoxyethylene (20) sorbitan monostearate*

The results of acute, short-term and long-term oral feeding studies furnished no evidence of carcinogenicity and were satisfactory. This enabled us to examine critically certain observations and subsequently to discount conclusions claiming to show that this ester might be capable of acting as a co-carcinogen under the particular condition of application to the skin of mice (Ewing and Tauber, 1965; WHO, 1964).

(viii) *Polyoxyethylene (8) stearate*

Satisfactory results from acute, short-term and long-term oral feeding studies were available to use. An increase in bladder-tumours has been observed in animals receiving 20 per cent or more of polyoxyethylene (8) stearate in their diet. All the animals that had tumours also had bladder stones but no bladder stones or tumours were observed at levels below 20 per cent. We accept that the observed tumours are attributable to the presence of bladder stones which do not occur at levels proposed to be used in bread and cakes—i.e. up to 0·5 per cent by weight (WHO, 1964).

(ix) *Cellulose ethers and sodium carboxymethyl cellulose*

Cellulose ethers (i.e. methyl, ethyl, hydroxyethyl and hydroxypropyl derivatives of cellulose) and sodium carboxymethyl cellulose are currently permitted for use in food excluding bread. We were informed that the cellulose ethers and sodium carboxymethyl cellulose are often used in conjunction as stabilisers/emulsifiers, at total amounts up to 5 per cent, in such products as ice-cream and "lollies", imitation creams, fruit squashes, sponges and meringues. Some doubts arose in 1957 about the safety of cellulose derivatives because it was found that repeated subcutaneous injection of a 2 per cent aqueous solution of sodium carboxymethyl cellulose into rats led to a high incidence of subcutaneous sarcomata (Lusky and Nelson, 1957). The results of further comprehensive long-term feeding tests in rats and in mice on sodium carboxymethyl cellulose and on methyl ethyl cellulose were submitted to us. We now agree that the toxicological evidence is adequate to permit the continued use in food of sodium carboxymethyl cellulose and cellulose ethers.

(x) *Dioctyl sodium sulphosuccinate*

We were informed that dioctyl sodium sulphosuccinate has been proposed by the manufacturers for use as a flavour and aroma enhancer in meat, fish, milk products, coffee and essential oils; as a wetting agent (e.g. for fumaric acid and edible gums); to prepare hop extracts; and as a potential bitter flavour. A level of 10 ppm is generally claimed as acceptable, though higher levels are required for use as a bitter flavour. It is also claimed that dioctyl sodium sulphosuccinate has fungicidal and bactericidal properties. There have been satisfactory short-term studies on several animal species and a long-term study in rats (Fitzhugh and Nelson, 1948). Dioctyl sodium sulphosuccinate is extensively used as a laxative (up to 300 mg. daily) in the U.S.A. We agree that though there are no toxicological objections to dioctyl sodium sulphosuccinate, because of the possibility that dietary intakes may reach the laxative dose, its use should not be permitted in basic items in the normal diet consumed by the greater part of the population, nor as a bitter flavour. We are however prepared to agree to the use of dioctyl sodium sulphosuccinate for specific purposes where there is a definite technological need.

(xi) *Microcrystalline cellulose*

We classified this substance in Group A because there was no evidence of physical or chemical degradation in the human intestine (Tusing *et al*, 1964).

7. Group B

(i) *Guar and gum ghatti*

The biological information for both substances where available was unsatisfactory (Booths *et al*, 1963). Adequate short-term studies in several species and a long-term study in at least one species are required on specified representative materials before the next review.

(ii) *Quillaia*

Quillaia has been used for about 100 years primarily to give a good head of foam on soft drinks which may thus contain up to 200 ppm of quillaia saponin—the active principle of quillaia. Saponins by injection are known to be haemolytic and to affect the central nervous system.

Acute oral overdosage of quillaia in man produces violent gastroenteritis, liver damage and haemolysis. Prolonged administration of quillaia at lower dosage may also give local gastro intestinal irritation which raises the possibility of absorption of saponin and the development of systemic effects. No formal long-term toxicological studies were available, but there have been no reports of acute saponin poisoning from the consumption of soft drinks (Kofler, 1932; Oser, 1966).

We are prepared to accept the continued use of quillaia at levels up to 200 ppm in soft drinks provided that B.P. material is used as such or in extract preparations (aqueous, ethanolic or isopropanolic). But adequate long-term studies including a particular study of the nature of the intestinal irritation must be carried out before the next review if the permitted use is to continue.

(iii) *Cross-linked, esterified and etherified modified starches*

According to the trade submissions, these products are regarded as technologically important and have been in use for 10 to 15 years at levels of 5 to 15 per cent in various manufactured foods, e.g. sauces, meat products and baby foods. The toxicological evidence in general is inadequate and does not extend beyond some *in vitro* digestibility studies and, at most, 90-day studies in rats. However the extent of modification is small in most cases, and we are prepared to advise that, for the time being the continued use be accepted of the specified modified starches listed (*a*)–(*f*) on the understanding that they are subject to review as soon as possible. In those cases (*d*)–(*f*) where the modification is relatively great, we believe there is a need for life-span studies in two species to exclude possible adverse long-term effects. We do not object to dextrinisation, acid-thinning or oxidation in conjunction with the various modifications.

(*a*) *Di-starch phosphate (starch modified by treatment with phosphoryl chloride)*

No relevant toxicological or chemical evidence was available to show that this modification produced an identical product to that obtained by treatment with sodium trimetaphosphate, which we classified as Group A. (see paragraph 6). Because the regulations of other countries permit a maximum treatment level of 0·1 per cent phosphoryl chloride, we are prepared to advise that starch modified to this extent be accepted provided adequate short-term studies on two species are carried out before the next review.

(*b*) *Phosphated di-starch phosphate* (starch treated with sodium tripolyphosphate and sodium trimetaphosphate)

High-dosage target organ studies showed some evidence of kidney and liver damage. The available short-term studies covered low dietary levels (3·5–5 per cent). Further short-term studies on at least two species, at higher dietary levels than this, and with special emphasis on kidney and liver pathology, are required before the next review.

(*c*) *Di-starch glycerol* (starch treated with epichlorhydrin)

The toxicological information was inadequate. Adequate short-term studies in two species with full histological and pathological investigations are required before the next review.

(*d*) *Starch acetates* (starch treated with acetic anhydride or vinyl acetate)

The toxicological studies were inconclusive as regards a no-effect level, although no obvious important lesions were found. In view of the comparatively large degree of modification, short-term and life-span studies on two species are required before the next review on compounds prepared by each route.

(*e*) *Acetylated di-starch glycerol* (starch treated with epichlorhydrin and acetic anhydride)

Short-term and long-term studies on two species with special emphasis on liver and kidney pathology and histology are required before the next review.

(*f*) *Acetylated di-starch adipate* (starch treated with acetic anhydride and adipic anhydride)

Some toxicological evidence was available but it was insufficient to establish a clear no-effect level. In view of the considerable modification, the unusual cross-linking agent and its use in infant foods we agreed that short-term and long-term studies on two species are required before the next review.

(iv) *Emulsifier YN* (ammonium phosphatides)

We were informed by the manufacturers that Emulsifier YN is widely employed in the chocolate industry to replace commercial lecithin as a viscosity reducing agent. The maximum level of use is 0·5 per cent by weight of the chocolate. We were provided with results of acute toxicity tests on several animal species, biochemical studies including metabolic studies in man and the rat, and short-term (45 weeks and 90 days) studies in the rat. The metabolic studies in rats showed Emulsifier YN to be broken down into normal food constituents and the acute toxicity tests disclosed non-toxicity at levels of 20g/kg body weight in rats and mice. We agreed not to object to the continued use of the Emulsifier YN but, because its use in chocolate could mean high and prolonged intakes by all age groups, we think long-term studies in rats or other species should be made before the next review and evidence be provided that Emulsifier YN experiences the same metabolic fate in man as in the rat and breaks down into normal food constituents.

(v) *Commercial mono- and di-glycerides of fatty acids including hydroxy fatty acids*

Very little toxicological information was available and we agreed that adequate data should be provided before the next review.

(vi) *Lactoglycerides*

Lactoglycerides are obtained either by esterification of mono- and di-glycerides from edible oils with lactic acid or by esterification of glycerol with a mixture of lactic acid and fatty acids from various sources. Consequently there is a range of commercial products containing varying proportions of tri-glycerides, diglycerides, monoglycerides, lactate esters of mono- and diglycerides, glyceryl lactate, free fatty acids, free lactic acid and glycerine. We were informed by the manufacturers that lactoglycerides can be used in or with fat, up to a level of 8 per cent of the combined weight of fat and the emulsifier, for such products as bread, cakes, ice-cream, whipped toppings and caramels. The current U.K. Regulations permit the use of lactoglycerides in bread as well as food in general. In considering the toxicological information we agreed that we would like to have seen data on acute toxicity. The evidence from short-term studies gave no grounds for suspicion but because of the incompleteness of the metabolic studies a long-term study on one species is essential and a long-term study on a second species is desirable (WHO, 1967 a).

(vii) *Diacetyl tartaric acid esters of mono- and diglycerides*

The method of manufacture (by reacting diacetyl tartaric acid anhydride with commercial mono- and di-glycerides of edible fats) leads to a range of products of heterogeneous composition. We were informed that diacetyl tartaric acid esters of glycerides are mainly used as an emulsifier in bakery fats (up to 30 per cent by weight) such fat being used to prepare bread, rolls, biscuits and cakes which thereby contain up to 1 per cent of this emulsifier by weight of the flour ingredient.

Diacetyl tartaric acid glyceride esters are currently permitted in the U.K. for use in food, including bread. Both tartaric and acetic acid and mono- and di-glycerides are well known dietary constituents. The esters showed a very low toxicity when given orally to animals. Radioisotype experiments showed that the tartaric acid moiety of the molecule was absorbed only to a small extent. The long-term studies were on one species only and with inadequate numbers of animals (WHO, 1967 a). Further long-term studies in two species with adequate numbers of animals were required. These should be made on material having a known combined diacetyl tartaric acid content (WHO, 1967 b).

(viii) *Polyglycerol esters of interesterified fatty acids of castor oil*

All the information supplied to us concerned the product of one manufacturer. We were informed that the product is used to prepare water-in-oil tin-greasing emulsions for the bakery trade and, at levels up to 0·4 per cent, to lower the viscosity of chocolate.

The product is a complex mixture of compounds most of them containing in the molecule one or more condensed fatty acid groups, one or more ester links, usually one or more ether linkages, several free hydroxyl groups and free glycerol. The toxicological evidence was reasonably satisfactory, but we consider that in view of an observed kidney and liver enlargement in rat and mouse studies

(*a*) more direct evidence of the metabolic fate of the major polymeric constituents is desirable; and,

(*b*) a short-term study in a species other than the rat is required to establish a no-effect level in a second species.

We noted that the manufacturers have commenced a 90-day feeding test in chickens and propose to conduct a radio-tracer study on the metabolic fate of their product in rats and in mice. We decided that the toxicological evidence so far submitted enables us to agree to advise that only the particular specified product submitted be retained as one of the permitted emulsifiers and stabilisers for use in chocolate. Although use as a direct ingredient in bread is excluded allowance should be made for surface "contamination" from tin-greasing operations. This agreement is subject to examination of the results of the required further investigations at or before the next review of emulsifiers and stabilisers.

(ix) *Propylene glycol alginates*

A range of products is produced by reacting moist alginic acid with propylene oxide at about 75°C. We were informed that the products are used as stabilisers and thickeners in sauces, lemon curd, pickles, marshmallows, soft drinks and beer at levels up to 1 per cent. The current Regulations permit the use of propylene glycol alginates in food excluding bread. No formal metabolic studies, but long-term studies were available for two species, although studies on mice extended only over twelve months (Nilson and Wagner, 1959). It would be desirable to determine a no-effect level in the mouse and rat.

(x) *Propylene glycol esters of fatty acids*

No long-term studies on these substances were available. *In vivo* and *in vitro* hydrolysis studies showed clear evidence that propylene glycol esters of fatty acids are hydrolysed and absorbed from the digestive tract at comparable rates and by similar mechanisms as glyceride esters of fatty acids (WHO, 1967 a). The biochemical fate of propylene glycol and the fatty acid moieties is equally well established. It would be desirable to determine a no-effect level in short-term studies in several species. Although by analogy with other fatty acid esters the propylene glycol esters might prove to be toxicologically acceptable, we require to see the results of the long-term studies on propylene glycol before the next review.

(xi) *Sorbitan esters of fatty acids*

We were informed that the sorbitan esters of fatty acids are proposed by manufacturers for use as anti-foaming agents and emulsifiers in a wide variety of foods including bread often in conjunction with polyoxyethylene sorbitan esters. Usage in bread is not at present permitted in the U.K.

(*a*) *Sorbitan monostearate* has been investigated in both short-term and long-term experiments (WHO, 1964). A further long-term study on a second species (e.g. the mouse) is required with particular attention being given to the histopathology of the liver and the gastrointestinal tract. We agree to the continued inclusion of this ester among the permitted emulsifiers and stabilisers subject to the results of the long-term study becoming available at or before the next review.

(*b*) *Sorbitan tristearate*

The results of long-term feeding studies on rats were available (WHO, 1964). A short-term study and a long-term study in a species other than the rat (e.g. the mouse) are required before the next review.

(*c*) *Sorbitan monopalmitate*

Results from short-term studies in two species and several long-term studies on the rat were available (WHO, 1964). A long-term study on a species other than the rat (e.g. the mouse) is required before the next review.

(*d*) *Sorbitan monolaurate and sorbitan mono-oleate*

Results from long-term studies on the rat were available, but results from short-term studies in rats and mice and a long-term study in a species other than the rat (e.g. the mouse) are required on each emulsifier before the next review (Treon, 1964).

(xii) (*a*) *Polyoxyethylene sorbitan tristearate*

Although we had been provided with adequate toxicological studies on the polyoxyethylene sorbitan monostearate less evidence was available for consideration in the case of the tristearate ester (WHO, 1964). Satisfactory results from some short-term studies and from a single long-term study on the rat were provided. Further short-term and long-term feeding tests on another species (e.g. the mouse) are necessary before the next review.

(*b*) *Polyoxyethylene sorbitan mono-oleate*

We agreed that the evidence from acute, short-term and long-term feeding studies was generally acceptable except that the latter were from a study on the rat only (WHO, 1964). In view of the co-carcinogenic activity of the ester under the particular condition of application to the skin of mice, results from long-term feeding studies on a species other than the rat are required before the next review.

(xiii) *Polyoxyethylene (40) stearate* has not shown any toxic effects in reasonably extensive tests but only one species (rat) has been studied in long-term tests (WHO, 1964). We require lifespan feeding studies in a second species such as the mouse.

(xiv) *Oxidatively polymerised soyabean oil*

We were provided with some specific studies on this substance as well as much collateral information related to "blown oils" generally (BIBRA, 1964) (See paragraph 9 (v)). The evidence does not suggest that this product is carcinogenic and gives some reassurance about its safety in use, particularly as only trace amounts will appear in food. We have agreed therefore to classify oxidatively polymerised soyabean oil into Group B but reclassification at the next review will depend upon what further information is forthcoming.

(xv) *Octadecylamine acetate and octadecylamine*

(*a*) Octadecylamine acetate is likely to occur in bread at a maximum level of 0·12 ppm when used as an anti-caking agent in a yeast food preparation. A 120-day feeding study on rats was available. Further information on its composition and purity is required now, and evidence of its metabolic fate in man before the next review, in addition to the information requested for octadecylamine. If found in bread at a level of 0·12 ppm we do not consider this to be a hazard to health.

(*b*) *Octadecylamine*

We were informed that not more than 0·5 ppm octadecylamine is likely to occur as a processing residue in food from the use of octadecylamine as a boiler water additive at a maximum level of 3 ppm in steam. The available long-term studies in rats were adequate to establish a no-effect level and absence of carcinogenicity but we require results of long-term studies in a second species before the next review.

8. **Group C**

Sodium carboxymethyl di-starch glycerol

Short-term studies on rats showed evidence of diarrhoea and loss of hair at all levels tested. We require at least a short-term study on rats to establish a no-effect level and it may subsequently be desirable to have results from long-term studies.

9. **Group D**

Brominated edible vegetable oils

We understand that the permitted levels of use in other countries are limited to a maximum of 200 ppm in the beverage as consumed and similar or lower levels are in use in some soft drinks in the U.K. Doubts were expressed by the Joint FAO/WHO Expert Committee on Food Additives in their 9th Report (1966) regarding possible cumulation of bromine in body lipids. We have been informed that in the last three years investigations have been carried out chiefly in Canada by the Food and Drugs Directorate and in the U.K. by the British Industrial Biological Research Association.

The investigations in the U.K. indicate that in rats and pigs considerable retention of bromine occurred at all levels tested and that its excretion was very slow. Thus a no-effect level had not been established. (BIBRA, 1970[a]). Evidence from the analysis of human tissues suggests that this finding also applies to man although no apparent adverse effects have been observed. However, the occurrence of considerable amounts of bromine as a tissue residue, particularly in children, is clearly undesirable (BIBRA, 1970[b]).

The early Canadian findings (Munro *et. al.*, 1969) suggested that high doses in rats, had some effect on the heart and this is confirmed by their further studies for lower dose levels. These heart lesions, reported by the Canadian workers have not been confirmed in all respects by the BIBRA investigations (BIBRA, 1970[a]).

We have therefore classified these materials into Group D and recommend that brominated edible vegetable oils should no longer be used in food.

10. Group E

(i) *Modified starches*

(*a*) *Bleached* (*lightly oxidised*) *starch*—bleached with potassium permanganate and containing up to 50 ppm residual manganese. No toxicological information was submitted. In view of the nature of the oxidising agent we think that this use would need to be considered as part of a review of the toxicity of manganese.

(*b*) *Acetylated di-starch phosphate*—starch treated with phosphoryl chloride and acetic anhydride. No toxicological information was submitted to enable an assessment to be made.

(*c*) *Starch sodium succinate, starch sodium octenyl succinate, starch aluminium octenyl succinate*

The available toxicological information was inadequate and we require at least properly conducted short-term studies in rats. Long-term studies may subsequently be desirable.

(*d*) *Hydroxypropyl starch*

No toxicological information was submitted.

(*e*) *Enzyme modified starches*

A wide range of products is possible within this description. We require more information about the products involved and the nature, purity and freedom from undesirable contaminants of the enzyme preparations used to make them.

(ii) *Polyglycerol esters of dimerised fatty acids of soyabean oil*

We were supplied with information concerning the product of one manufacturer. We were informed that this is recommended for use in tin-greasing emulsions (max. 3 per cent); pastry margarine (max. 0·2 per cent) and in bakery compounds (max. 1 per cent).

Metabolic studies were inadequate, there were no acute toxicity tests and short-term and long-term studies gave somewhat conflicting results (Aes-Jorgensen *et al*, 1956). We consider that this emulsifier should not continue to be permitted in food until at least a satisfactory specification is provided together with the results of short-term (90-day) studies on several animal species to establish no-effect levels using, of course, the specified material.

(iii) *Propylene glycol esters of fatty acids and lactic acid*

Very little information was available about composition and toxicology. We would consider it essential that the alcohol moiety consisted of propane-1, 2-diol because the propane-1, 3-diol has been shown to have teratogenic activity in the developing chick embryo.

(iv) *Blown oils*

The available information on "blown oils" other than oxidatively polymerised soyabean oil was inadequate for toxicological assessment. Some of the information on heat treated and oxidised fats points to the production of toxic materials, certain of which may have a carcinogenic potential (Aes-Jorgensen *et al*, 1956). We have therefore agreed to classify "blown oils" generally into Group E.

(v) *Sodium mono-stearyl fumarate*

Because of the proposed main use of sodium stearyl fumarate as a bread-and cake-crumb softener, properly conducted long-term studies on two animal species and biochemical studies on its metabolic fate in man are required before we could consider this product for addition to the permitted list of emulsifiers.

(vi) *Sucrose esters of fatty acids and sucroglycerides*

We were informed that the manufacturer wishes to sell the following in the U.K. for use in various foods (including bread) at levels up to 4 per cent by weight:

> Sucrose monopalmitate, dipalmitate, monostearate, distearate.
> Sucroglycerides from palm oil, from hydrogenated palm oil, from tallow, from lard.

There is a need for information on residual methyl alcohol as a potential contaminant.

Our main concern is about dimethylformamide, which in the data submitted was present as a residual solvent in the esters. Dimethylformamide has been shown to cause liver-damage in acute and short-term studies, but has not been subjected to long-term tests. Some of the short-term studies were carried out on material containing 300–400 ppm dimethylformamide while the major part of the toxicological studies were conducted on material containing 50 ppm dimethylformamide.

The toxicological evidence derived from experiments using sucroglycerides containing such small amounts of dimethylformamide was reasonably adequate (Chiancone *et al*, 1963; Oshima and Kajiwara, 1960; Tudisco and Chiancone, 1965). Theoretically the pure ester might be held to present no intrinsic toxicological problem.

We understand that sucrose esters can be produced to contain no more than 50–100 ppm of dimethylformamide. Nevertheless, we consider that sucrose esters and sucro-glycerides should not be added to the permitted list of emulsifiers until information is provided about:

(*a*) limits of methyl alcohol residues in the specifications of the esters;
(*b*) a satisfactory specification for the maximum content of dimethylformamide;
(*c*) further short-term and long-term toxicological studies on dimethylformamide depending on the residual amounts found in these products.

(vii) *Citric acid and fatty acid esters of glycerol* (citroglycerides)

The toxicological information submitted referred only to *in-vitro* and digestibility studies without any supporting adequate short-term or long-term studies (WHO, 1967a). We were unable on this evidence to accept the statement in the 10th Report of the Joint FAO/WHO Expert Committee that the substance is metabolised completely by man into components which are normal constituents of the diet and have classified it into Group E. Re-classification at the time of the next review will depend on the availability of adequate information on the safety in use of this substance.

Summary of recommendations

1. *We consider* that specifications should always be laid down for substances accepted for use in food. (Paragraph 3).

2. *We recommend* that only those substances which we have placed in Groups A and B should be allowed in food. In bread there should be permitted only stearyl tartrate, commercial mono- and di-glycerides of fatty acids excluding hydroxy fatty acids, and diacetyl tartaric acid esters of mono- and di-glycerides. Polyoxyethylene (8) stearate may require further consideration.

Sorbitan- and polyoxyethylene sorbitan-esters of fatty acids and dioctyl sodium sulphosuccinate should not be permitted to be used freely. (Paragraph 5).

3. We classified the substances submitted to us as shown below. Those marked with a dagger (†) are already permitted in food either specifically or generically.

Group A

†*Agar*

†*Alginic acid*, †*calcium alginate*, †*sodium alginate*, *ammonium alginate*, *potassium alginate*

†*Carrageen*

†*Acacia*, †*karaya*, †*tragacanth* and †*carob* gums

†*Pectin*, †*calcium pectate*, †*sodium pectate*

†*Amylose* and †*amylopectin starches*

†*Acid-thinned starches*
White and yellow† *dextrins*

†*Bleached* (*lightly oxidised*) *starches*—using chlorite, hypochlorite, hydrogen peroxide, peracetic acid

†*Hypochlorite oxidised starch*

†*Di-starch phosphate* (modified by treatment with sodium trimetaphosphate)

†*Stearyl tartrate*

†*Commercial mono- and di-glycerides of fatty acids excluding hydroxy fatty acids*

†*Acetoglycerides*

†*Tartaric acid glycerides*

†*Polyglycerol esters of fatty acids* (specified)

†*Polyoxyethylene (20) sorbitan*—

(*a*) *monolaurate*
(*b*) *monopalmitate*
(*c*) *monostearate*

but not in basic items of the normal diet of the greater part of the population.

Polyoxyethylene (8) stearate

†*Cellulose ethers* and †*sodium carboxymethyl cellulose*

Dioctyl sodium sulphosuccinate—but not in basic items of the normal diet of the greater part of the population or as a bitter flavour.

Microcrystalline cellulose

Group B

†*Guar* and †*gum ghatti*. A specification is required now for gum ghatti and adequate short-term studies and a long-term study are required on both substances before the next review.

†*Quillaia*—provided adequate long-term studies including a particular study of the nature of the gastrointestinal irritation are carried out before the next review.

†*Modified starches*

(*a*) *Di-starch phosphate* (modified by treatment with phosphoryl chloride)
(*b*) *Phosphated di-starch phosphate*
(*c*) *Di-starch glycerol*
(*d*) *Starch acetates*
(*e*) *Acetylated di-starch glycerol*
(*f*) *Acetylated di-starch adipate*

All subject to further toxicological studies before the next review.

†*Emulsifier YN* at a maximum level of 0·5 per cent by weight in chocolate. Long-term studies in animals and metabolic studies in man are required before the next review.

†*Commercial mono- and di-glycerides of fatty acids including hydroxy fatty acids*—specifications are required now and results from short-term and long-term studies before the next review.

†*Lactoglycerides*—provided results from a long-term study on at least one animal species are available at the next review.

†*Diacetyl tartaric acid esters of mono- and di-glycerides*
Further long-term studies in two species with adequate numbers of animals on material having a known combined diacetyltartaric acid content of about 30 per cent are required before the next review.

†*Polyglycerol esters of interesterified fatty acids of castor oil*
Pending receipt of the results of the metabolic studies on rats and mice and 90-day feeding tests on chickens which are known to be in progress.

†*Propylene glycol alginates*

†*Propylene glycol esters of fatty acids*

†*Sorbitan esters of fatty acids:*

(*a*) *Sorbitan monostearate*
(*b*) *Sorbitan tristearate*
(*c*) *Sorbitan monopalmitate*
(*d*) *Sorbitan monolaurate*
(*e*) *Sorbitan mono-oleate*

subject to further toxicological studies before the next review.

†*Polyoxyethylene sorbitan tristearate*

†*Polyoxyethylene sorbitan mono-oleate*
subject to further toxicological studies before the next review.

Polyoxyethylene (40) stearate—long-term studies in a species other than the rat (e.g. the mouse) are required.

†*Oxidatively polymerised soyabean oil* for tin-greasing emulsions—specific toxicological studies with this material.

Octadecylamine acetate (up to 0·12 ppm in bread) and *octadecylamine* (up to 0·5 ppm in food)—subject to further toxicological studies.

Group C

†*Sodium carboxymethyl di-starch glycerol*

Group D

†*Brominated edible vegetable oils*

Group E

†*Modified starches:*

(*a*) *Starch bleached with potassium permanganate*

This would need to be considered as part of a review of the toxicity of manganese.

(*b*) *Acetylated di-starch phosphate*

(*c*) *Starch sodium succinate, starch sodium octenyl succinate, starch aluminium octenyl succinate* (*d*) *Hydroxypropyl starch*

(*e*) *Enzyme modified starches*

Polyglycerol esters of dimerised fatty acids of soyabean oil

Propylene glycol esters of fatty acids and lactic acid

Blown oils—other than oxidatively polymerised soyabean oil

Sodium monostearyl fumarate

Sucrose esters of fatty acids and sucroglycerides

Citric acid and fatty acid esters of glycerol (citroglycerides).

REFERENCES

In the interest of brevity, only a restricted list of published references to the biological data has been provided. Nevertheless, the Committee had access to a large volume of scientific information all of which has been critically examined and, so far as is possible, references to this evidence may be obtained on request.

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